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# United States Patent [19]

Lam

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[54] **OSTIAL STENT FOR BIFURCATIONS**

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[73] Assignee: **Advanced Cardiovascular Systems, Inc.**, Santa Clara, Calif.

[21] Appl. No.: **677,248**

[22] Filed: **Jul. 9, 1996**

**Related U.S. Application Data**

[63] Continuation of Ser. No. 162,579, Dec. 2, 1993, abandoned.

[51] **Int. Cl.**[6] ..... **A61M 29/00**

[52] **U.S. Cl.** ..... **606/194**; 604/104

[58] **Field of Search** ..... 606/191–192, 606/194–195, 198, 108; 623/1, 12; 604/96, 104–106, 284

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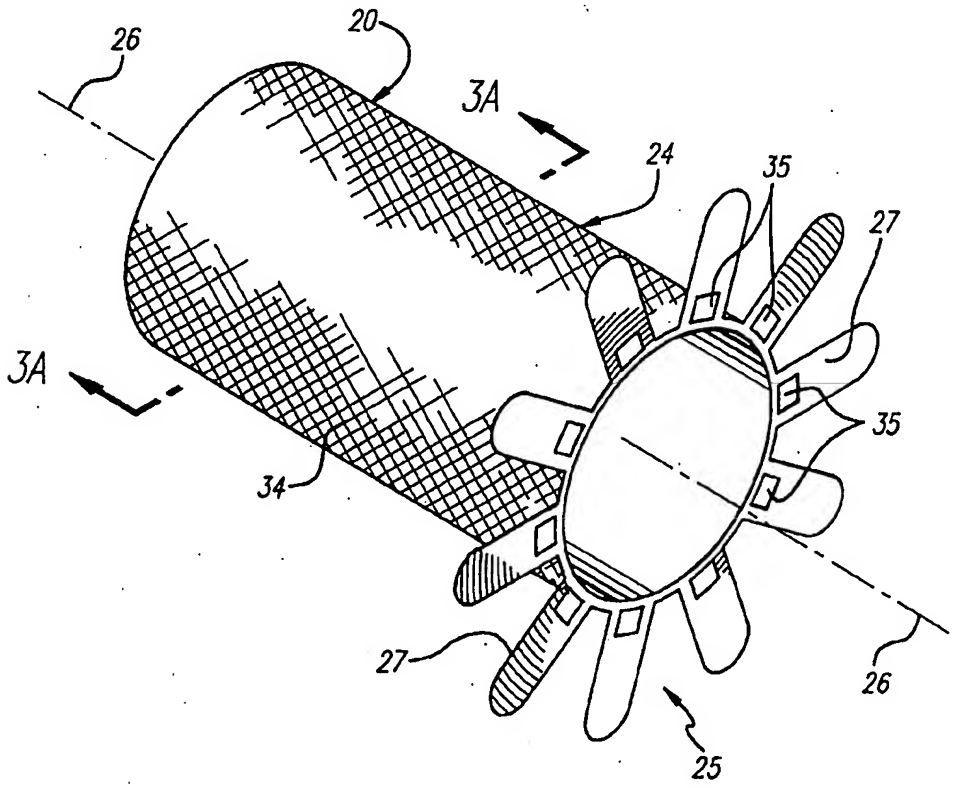
[57] **ABSTRACT**

A method and apparatus for repairing a vessel at a bifurcation without obstructing blood flow through the bifurcation, wherein an expandable ostial stent comprises a tubular body and a deformable flaring portion. Repair of a bifurcated vessel is accomplished by positioning the expandable ostial stent within a diseased portion of the bifurcation so that the flaring portion caps the ostium and the tubular body is seated within a side branch to the bifurcation, thereby completely repairing the vessel at the bifurcation without occluding blood flow.

**13 Claims, 5 Drawing Sheets**



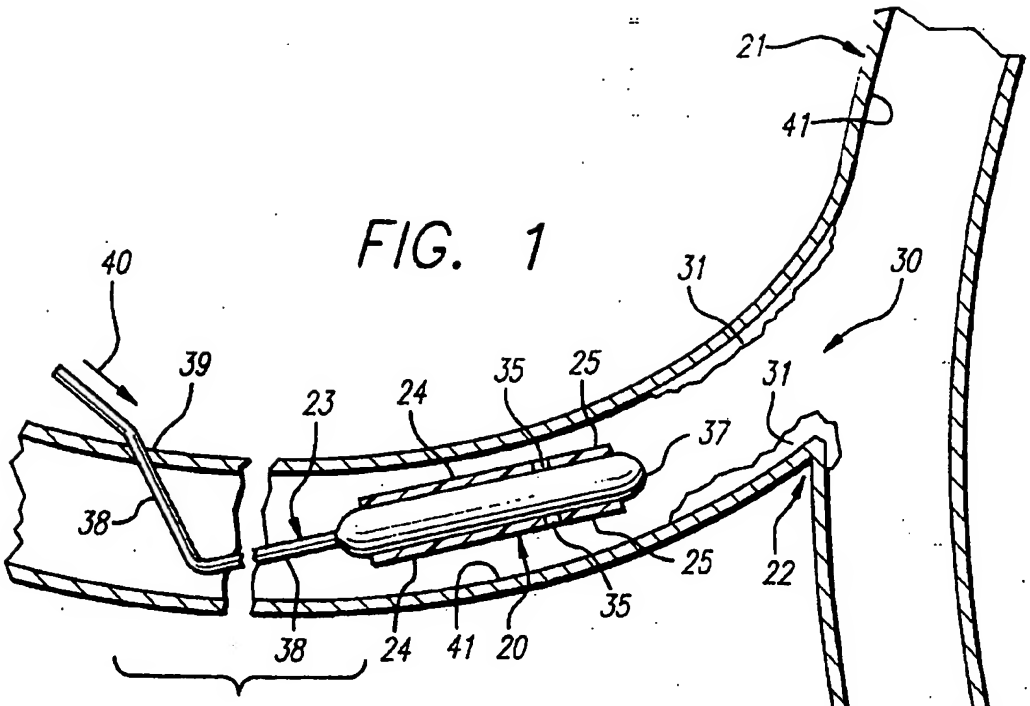



FIG. 1

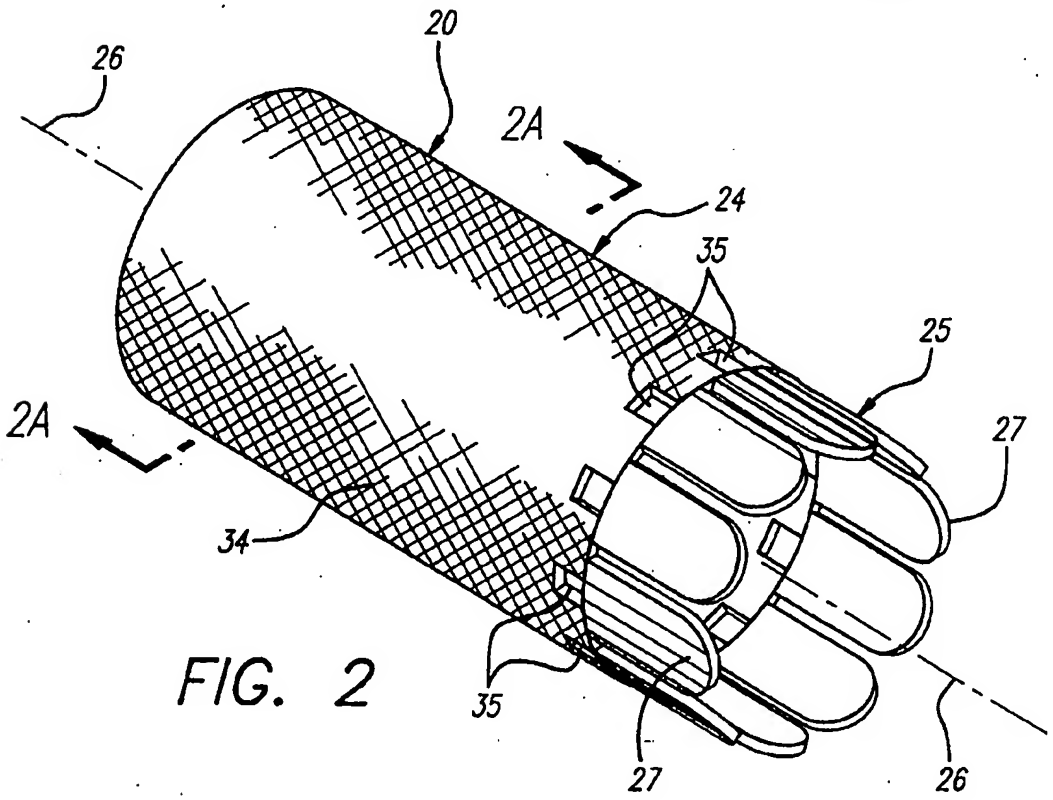



FIG. 2

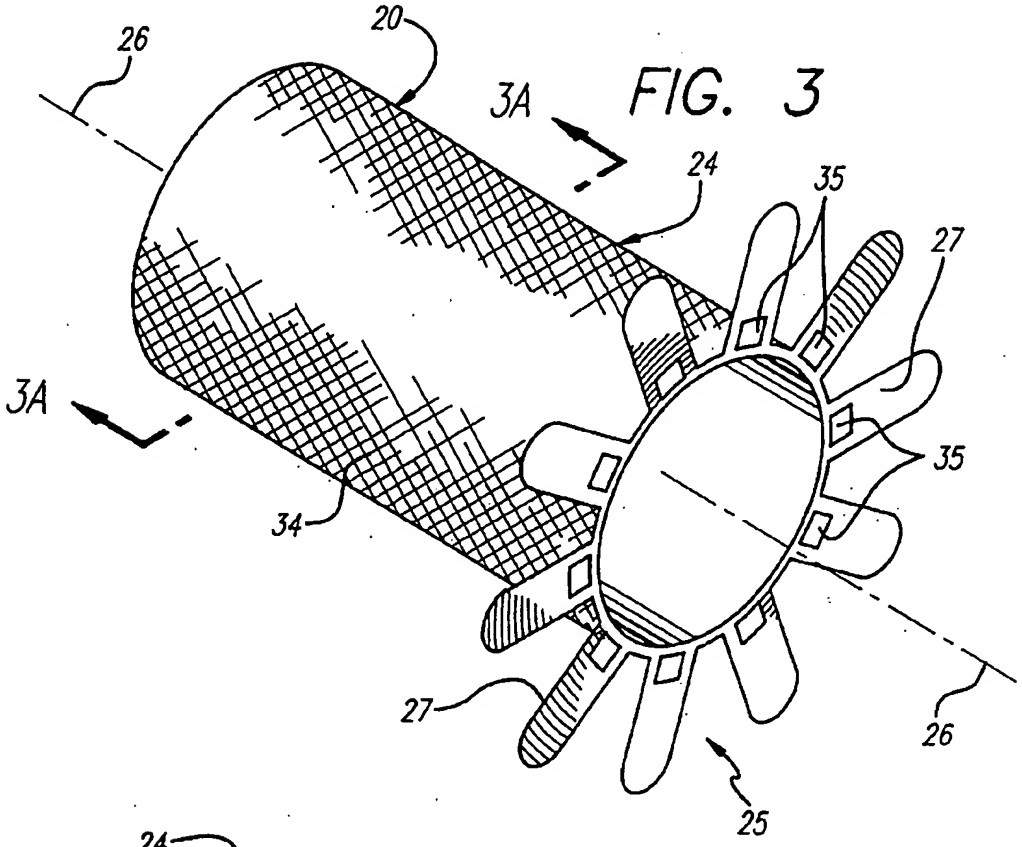



FIG. 3

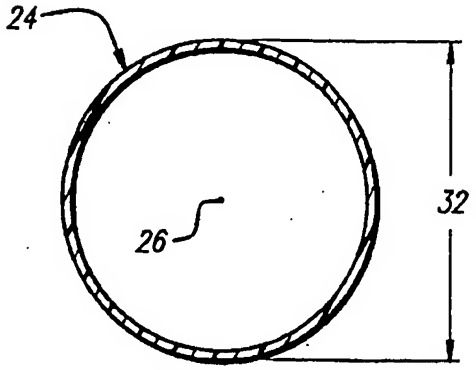



FIG. 2A

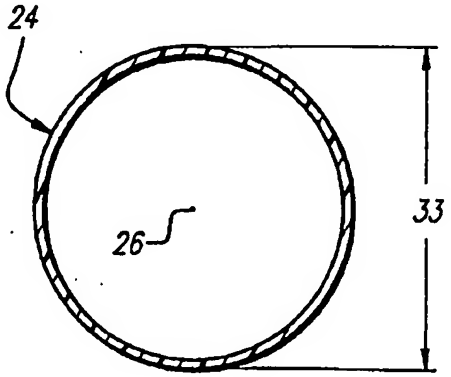



FIG. 3A

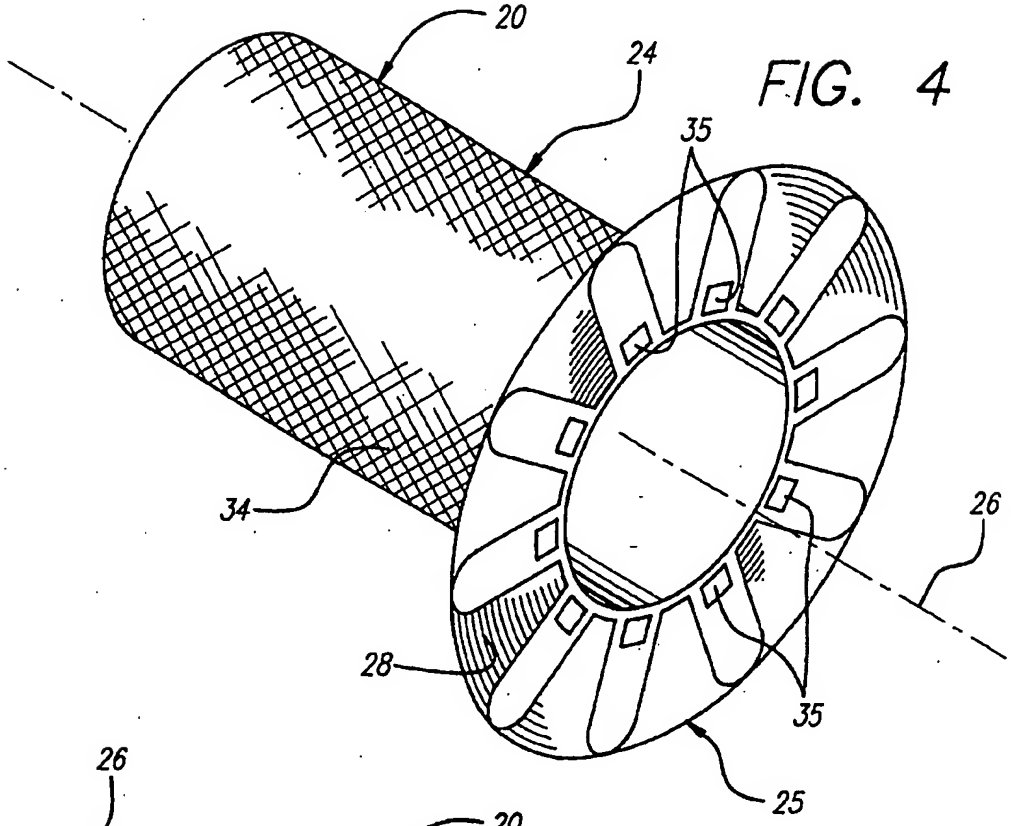



FIG. 4

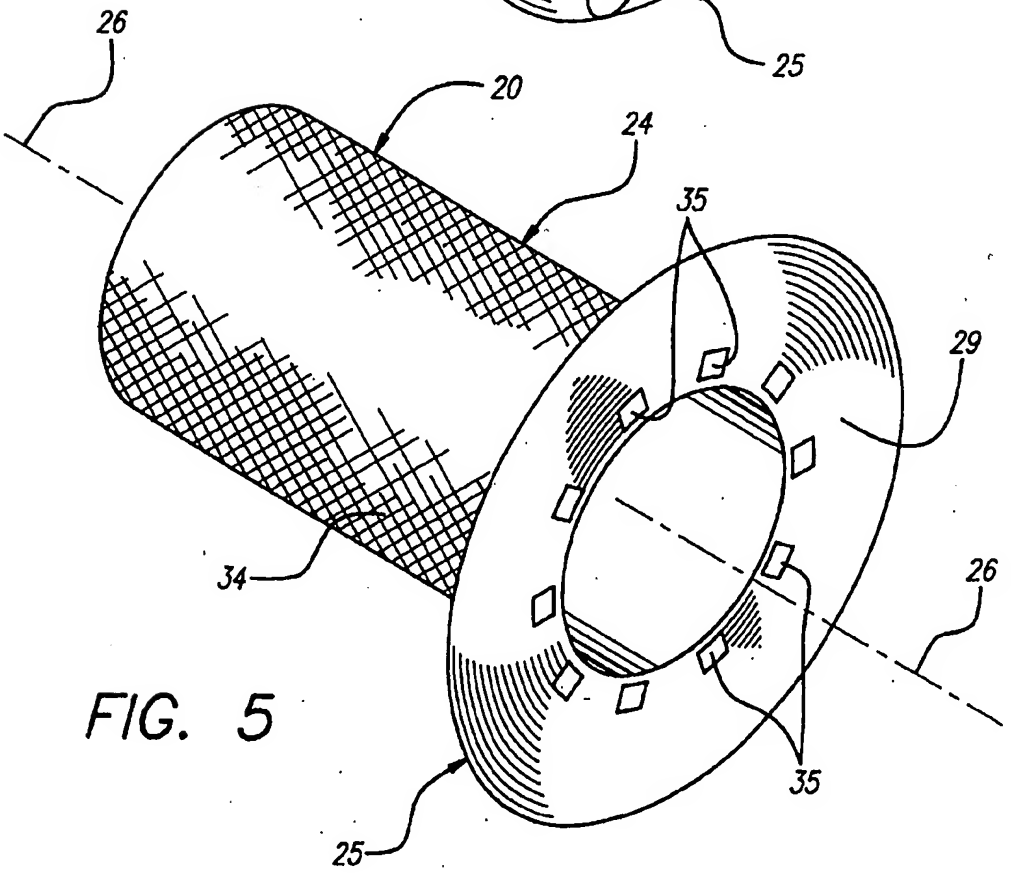



FIG. 5

FIG. 6

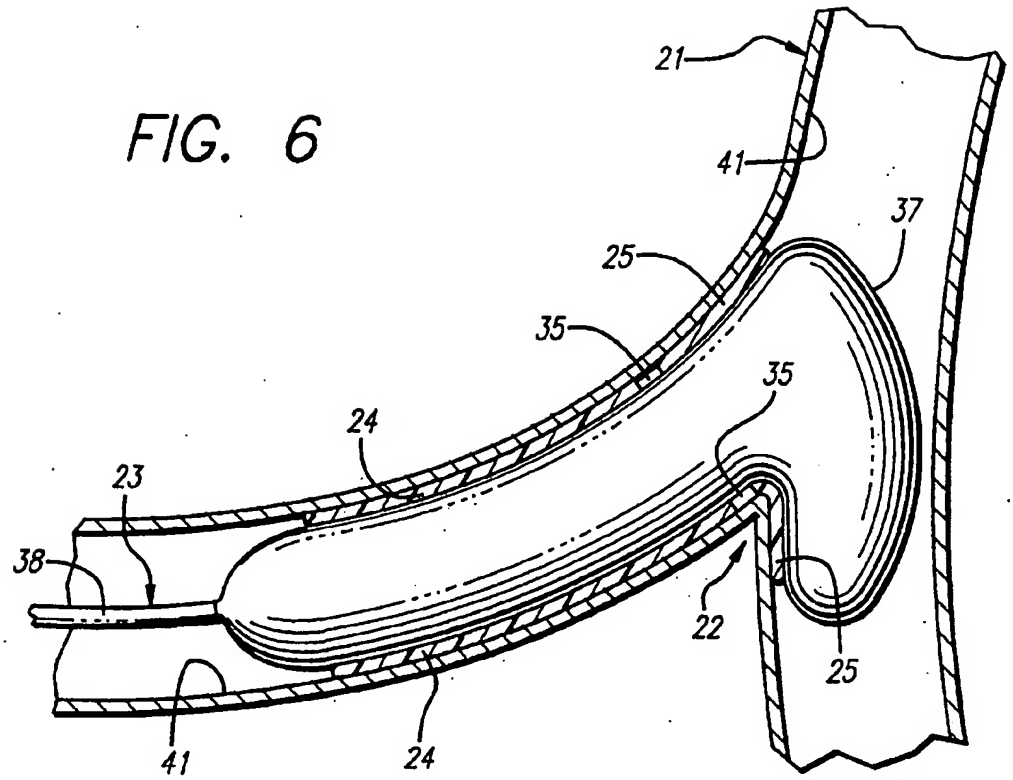

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FIG. 7

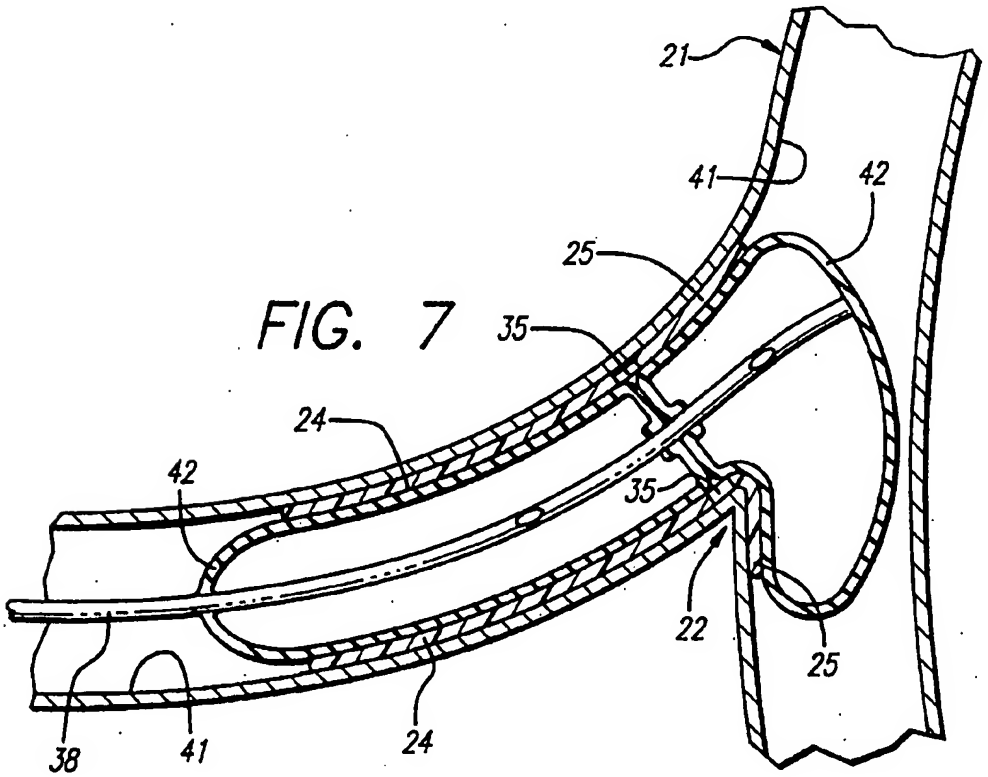
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FIG. 8

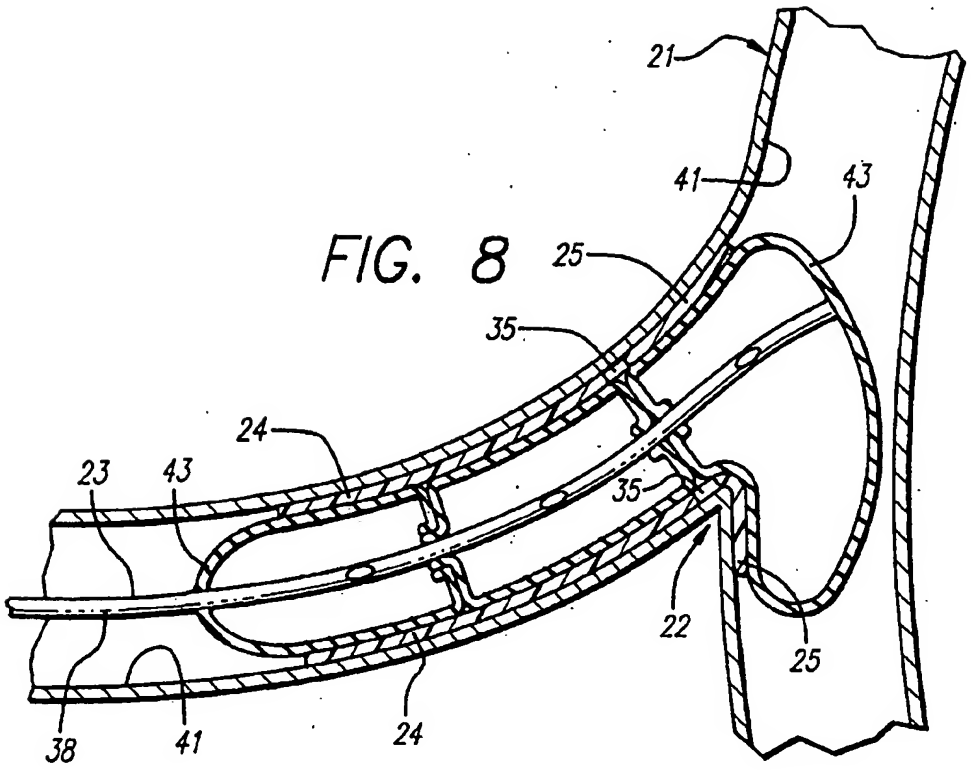
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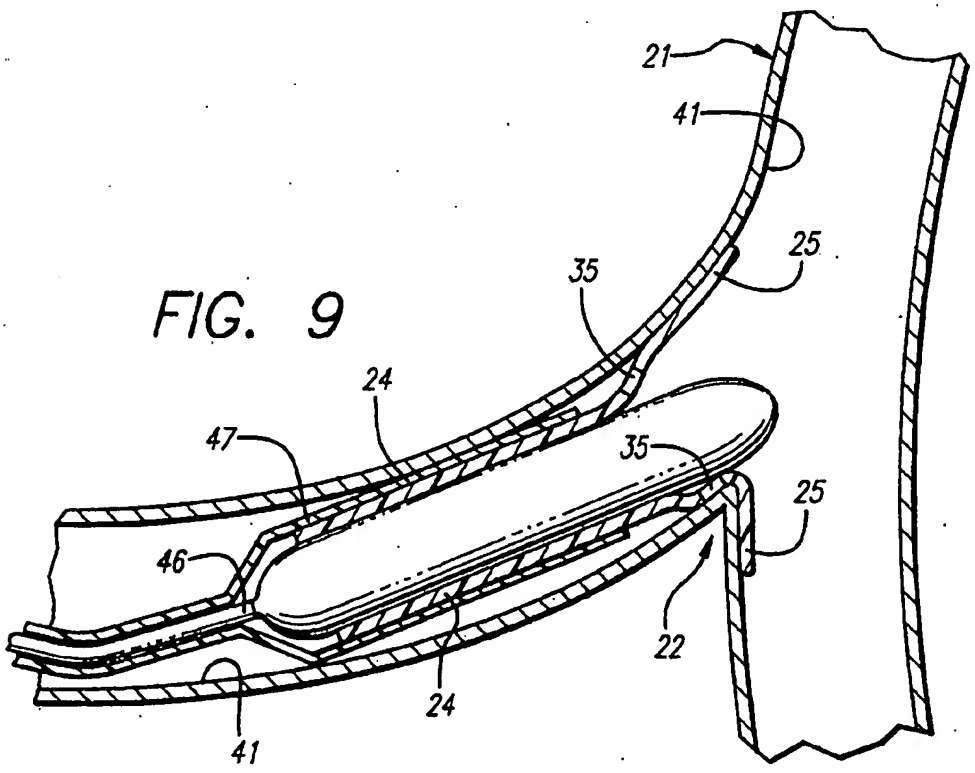
FIG. 9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# OSTIAL STENT FOR BIFURCATIONS

This application is a continuation of application Ser. No. 08/162,579 filed Dec. 2, 1993, now abandoned.

## BACKGROUND OF THE INVENTION

1. Field of the Invention

The invention relates to a stent for use at a bifurcation and, more particularly, an expandable and deformable stent which is particularly useful for repairing bifurcated blood vessels that are diseased, and a method or apparatus for implantation.

2. Prior Art

Stents conventionally repair blood vessels that are diseased and are generally hollow and cylindrical in shape and have terminal ends that are generally perpendicular to its longitudinal axis. In use, the conventional stent is positioned at the diseased area of a vessel and, after placement, the stent provides an unobstructed pathway for blood flow.

Repair of vessels that are diseased at a bifurcation is particularly challenging since the stent must overlay the entire diseased area at the bifurcation, yet not itself occlude blood flow. Therefore, the stent must, without occluding blood flow, overlay the entire circumference of the ostium to a diseased portion and extend to a point within and beyond the diseased portion. Where the stent does not overlay the entire circumference of the ostium to the diseased portion, the stent fails to completely repair the bifurcated vessel. Where the stent overlays the entire circumference of the ostium to the diseased portion, yet extends into the junction comprising the bifurcation, the diseased area is repaired, but blood flow is occluded in other portions of the bifurcation. Moreover, by extending into the junction comprising the bifurcation, the stent may block access to portions of the bifurcated vessel that require performance of further interventional procedures.

Conventional stents are designed to repair areas of blood vessels that are removed from bifurcations and, since a conventional stent generally terminates at right angles to its longitudinal axis, the use of conventional stents in the region of a vessel bifurcation may result in blocking blood flow of a side branch or fail to repair the bifurcation to the fullest extent necessary. The conventional stent might be placed so that a portion of the stent extends into the pathway of blood flow to a side branch of the bifurcation or extend so far as to completely obstruct blood flow in a side branch. The conventional stent might alternatively be placed proximal to, but not entirely overlaying the circumference of the ostium to the diseased portion. Such a position of the conventional stent results in a bifurcation that is not completely repaired. The only conceivable situation that the conventional stent, having right-angled terminal ends, could be placed where the entire circumference of the ostium is repaired without occluding blood flow, is where the bifurcation is formed of right angles. In such a scenario, extremely precise positioning of the conventional stent is required. This extremely precise positioning of the conventional stent may result with the right-angled terminal ends of the conventional stent overlying the entire circumference of the ostium to the diseased portion without extending into a side branch, thereby completely repairing the right-angled bifurcation.

To circumvent or overcome the problems and limitations associated with conventional stents in the context of repairing diseased bifurcated vessels, a stent that consistently overlays the entire circumference of the ostium to a diseased portion, yet does not extend into the junction comprising the bifurcation, may be employed. Such a stent would have the advantage of completely repairing the vessel at the bifurcation without obstructing blood flow in other portions of the bifurcation. In addition, such a stent would allow access to all portions of the bifurcated vessel should further interventional treatment be necessary.



## SUMMARY OF THE INVENTION

The invention provides an ostial stent that completely repairs a vessel at a bifurcation without obstructing blood flow in other portions of the bifurcation, thereby allowing access to all portions of a bifurcated vessel should further interventional treatment be necessary. The invention also provides a method and apparatus for implanting the ostial stent.

The present invention is based on utilization of an ostial stent comprising an expandable tubular body and an end portion that is capable of being flared. To achieve the desired result of completely repairing a bifurcated vessel without occluding blood flow, the ostial stent is placed within the bifurcated vessel with its flaring portion, flared open, at the ostium to the diseased portion and tubular body of the ostial stent extending within and beyond the diseased portion.

The tubular body of the ostial stent capable of radial expansion. That is, the cross-sectional area of the ostial stent may be increased. The tubular body may comprise a geometric pattern or structural configuration that facilitates the radial expansion. In a preferred embodiment, the cross-sectional area is increased by means of exerting force upon the internal walls comprising the tubular body.

It is contemplated that the tubular body have adequate radial strength since the tubular body must have sufficient radial strength so that it retains its pre-expanded cross-sectional area, and after radial expansion, have sufficient radial strength so that it retains its expanded cross-sectional area. Adequate radial strength may be accomplished in part through the geometric structural configuration chosen for the tubular body and in part through the selection of material comprising the tubular body. Regarding the material of the tubular body, it is contemplated that the material have a low metal-to-space ratio.

The flaring portion of the ostial stent is continuous from the tubular body and it may be comprised of the same material as the tubular body, or the materials may differ. In addition, the flaring portion and tubular body may be formed as one piece or comprise two or more separate and distinct parts which have been attached.

The flaring portion is capable of expanding and may embody a plurality of individual petals that are each individually capable of adopting an undeformed configuration that is substantially parallel to the longitudinal axis of the stent and a deformed configuration that is unparallel to and at some angle slanting away from the longitudinal axis. It is contemplated that the flaring portion be capable of deforming throughout its length to varying degrees so that the flaring portion conforms to the irregular walls comprising an ostium. It is also contemplated that the individual petals may be connected by a thin malleable material that enhance the conforming capability of the flaring portion. In the alternative, the flaring portion may embody material that accomplishes the flaring function, yet has no recognizable pedals. In a preferred embodiment, deformation of the flaring portion may be accomplished by exerting a force upon the inside walls comprising the flaring portion.

It is also contemplated that radiopaque markers be formed in or attached to the ostial stent and placed so as to mark the joining line between the flaring portion and the tubular body. In addition, radiopaque markers could be placed to mark the circumferential location of each of the pedals that form the flaring portion. Marking the ostial stent in this way facilitates proper placement and orientation of the ostial stent within the bifurcated vessel.

Placement of the ostial stent within a diseased bifurcated vessel involves radially expanding the tubular body and expanding and deforming the flaring portion and may be useful in unobstructing occluded vessels or attaching the ostial stent in the area of an aneurysm. Radial expansion of the tubular body allows it to substantially conform, where necessary, to the inner walls of the bifurcated vessel, thereby seating the ostial stent within the bifurcated vessel. The flaring portion is deformed so that it substantially conforms to and "caps" the ostium to the diseased portion of the bifurcation, thereby resulting in firmly securing the ostial stent at the bifurcation.

Deployment of the ostial stent can be accomplished through the utilization of balloon catheters. The ostial stent is loaded onto the balloon of a balloon catheter with the flaring portion of the ostial stent configured to be unexpanded and substantially parallel to the longitudinal axis of the ostial stent and the tubular body in an unexpanded configuration. The ostial stent may be placed on the balloon so that its flaring portion is loaded on the distal portion of the balloon, and the tubular body is loaded on the proximal portion of the balloon. It is also contemplated that, depending upon the application, the ostial stent may be placed upon the balloon with its flaring portion located on the proximal end of the balloon and its tubular body loaded on the distal portion of the balloon.

The balloon catheter loaded with the ostial stent is advanced to the location of the diseased bifurcated vessel and by means of radiography, precise positioning of the ostial stent is achieved. Through the use of radiography, the location of the radiopaque markers which mark the ostial stent, can be ascertained and the ostial stent can be precisely positioned within a vessel.

After the ostial stent is positioned within the diseased bifurcated vessel, balloon catheters are employed to secure the ostial stent in position. By expanding the balloon carrying the ostial stent, the tubular body is seated within the diseased portion of the bifurcated vessel extending away from the bifurcation and the flaring portion is configured to "cap" the ostium to the diseased portion of the vessel. In the alternative, a series of various sized and shaped balloon catheters can be employed to configure the ostial stent so that it seats within and "caps" the ostium to the diseased portion of the bifurcation or a bi- or tri-balloon system may be employed to properly implant the tubular body and flaring portion of the ostial stent.

In another embodiment of the invention, the tubular body and flaring portion are fabricated from a memory-retaining metal, such as Nickel-Titanium (NiTi). At a cold temperature, the tubular body would be in an unexpanded condition, and the flaring end would be unexpanded and substantially parallel to the longitudinal axis of the ostial stent. At an increased temperature, the tubular body expands to seat within the diseased portion of the bifurcated vessel, and the flaring portion expands and deforms to "cap" the ostium to the diseased portion of the bifurcation. At a patient's normal body temperature, the ostial stent retains an expanded and deformed configuration, thereby sustaining a seated and "capped" position within the bifurcated vessel.

Advancement of a memory-retaining ostial stent to a diseased bifurcated vessel can be accomplished by means of a balloon catheter. During advancement, the memory-retaining stent can be maintained at a cold temperature. Thereafter, the stent would be subjected to an increased temperature so that the stent takes its expanded end deformed configuration.

It is also contemplated that only a portion of the ostial stent comprises memory-retaining material. Deformation or expansion of the portion of the ostial stent that is not memory-retaining may be achieved by means of balloon expansion.

In another embodiment, the ostial stent is comprised of spring-like material and is loaded in a retaining sleeve so as to place the tubular body in an unexpanded configuration and the flaring portion in a configuration that is unexpanded and substantially parallel to the longitudinal axis of the ostial stent. Upon removal of the retaining sleeve, the tubular body expands and the flaring portion opens, thereby securing the ostial stent within the diseased portion of the bifurcated vessel.

Advancement of the spring-like ostial stent to the site of a diseased bifurcated vessel may also be accomplished by a balloon catheter. In this embodiment, the spring-like ostial stent may be placed within a retaining sleeve and loaded upon the balloon of the balloon catheter. After advancement of the spring-like ostial stent to the site of the diseased bifurcated vessel, expansion of the tubular body and expansion and deformation of the flaring portion is achieved by removing the retaining sleeve.

It is also contemplated that only a portion of the ostial stent comprises spring-like material. Deformation or expansion of the portion of the ostial stent that is not comprised of spring-like material may be accomplished by means of balloon expansion.

Other features and advantages of the present invention will become apparent from the following detailed description, taken in conjunction with the accompanying drawings, which illustrate, by way of example, the principles of the invention.

## BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** depicts a partial cross-sectional view, illustrating an ostial stent loaded upon a balloon catheter during advancement of the ostial stent to the site of a diseased bifurcated vessel.

FIG. **2** depicts a perspective view of one embodiment of the present invention, illustrating an ostial stent in an unexpanded and undeformed configuration.

FIG. **2***a* illustrates a cross-sectional view taken along line **2***a*–**2***a* of an unexpanded and undeformed ostial stent.

FIG. **3** depicts a perspective view of one embodiment of the present invention, illustrating an ostial stent in an expanded and deformed configuration.

FIG. **3***a* illustrates a cross-sectional view taken along line **3***a*–**3***a* of an expanded and deformed ostial stent.

FIG. **4** depicts a perspective view of an alternate embodiment of the present invention, illustrating an ostial stent in an expanded and deformed configuration.

FIG. **5** depicts a perspective view of another embodiment of the present invention, illustrating an ostial stent in an expanded and deformed configuration.

FIG. **6** depicts a partial cross-sectional view of the stent of FIGS. **2** and **3**, illustrating a preferred method of expansion and deformation of an ostial stent.

FIG. 7 depicts a partial cross-sectional view of the stent of FIGS. 2 and 3, illustrating an alternate method of expansion and deformation of an ostial stent.

FIG. 8 depicts a partial cross-sectional view of the stent of FIGS. 2 and 3, illustrating another method of expansion and deformation of an ostial stent.

FIG. 9 depicts a partial cross-sectional view of a stent comprising spring-like material, illustrating a method of expansion and deformation of an ostial stent comprising spring-like material.

## DETAILED DESCRIPTION

As is shown in the drawings, which are included for purposes of illustration and not by way of limitation, the invention is embodied in an ostial stent **20** (FIG. **1**) and provides means to completely repair a diseased blood vessel **21** at a bifurcation **22**. Conventional stents are limited in structure to completely repair diseased blood vessels at a bifurcation. Placement of conventional stents in the region of a bifurcation for the purpose of repairing a diseased vessel may result in the conventional stent not entirely repairing the diseased region or the conventional stent extending into the junction comprising the bifurcation, thereby obstructing blood flow. The ostial stent **20** of the present invention is capable of completely repairing a diseased bifurcated vessel **21** without obstructing blood flow in the other portions of the bifurcation **22**. Thus, the ostial stent provides a patient with superior means to repair a diseased bifurcated vessel **21** and leaves the bifurcated vessel **21** in a condition amenable to further interventional procedures.

The present invention (FIG. **1**) accomplishes complete repair of a diseased vessel **21** at its bifurcation **22** by means of its novel structure and method of deployment. The dimensions and characteristics of the ostial stent **20** are selected to assure proper placement within and complete repair of the diseased bifurcated vessel **21**. Similarly, the dimensions and characteristics of the deployment mechanism utilized to deploy the ostial stent **20** are dependent upon the application.

The ostial stent **20** (FIG. **2**) has a tubular body **24** and a flaring portion **25** and may be comprised of one piece or two or more connected parts. The flaring portion **25** is continuous from and may be greater than, less than, or equal in length to the tubular body **24** of the ostial stent. In FIGS. **2** and **3** and by way of example, the flaring portion **25** is shown to be less in length than the tubular body **24**.

The material and structure of the ostial stent **20** is selected so that the ostial stent **20** is expandable and has sufficient radial strength to retain its shape. The material of the tubular body **24** may be the same as that chosen for the flaring portion **25**, or the material may differ. Irrespective of whether or not the materials of the tubular body **24** and the flaring portion **25** are the same, it is contemplated that the materials have a low metal-to-space ratio. The choice of material, however, must be such that it enables the tubular body **24** to achieve a pre-expanded **32** and a post-expanded **33** diameter (see FIGS. **2***a*, **3***a*) and to retain its pre-expanded and expanded shape. Likewise, the structural configuration must be chosen so that the ostial stent **20** possesses expansion and shape retention characteristics. It is contemplated, therefore, that the ostial stent **20** may possess a tubular structure with some geometric pattern **34** that facilitates shape retention and expansion.

The flaring portion **25** is capable of expanding and may be comprised of individual pedals **26** or in the alternative and as shown in FIGS. **4** and **5**, the flaring portion **25** may comprise malleable material **28**, **29** that enhances the conforming capabilities of the flaring portion. Therefore, in order to enhance conforming capabilities, the flaring portion may be comprised of pedals connected by malleable connecting material **28** or entirely of malleable material **29**.

Prior to deformation, the flaring portion **25** is substantially parallel to the longitudinal axis **26** of the ostial stent **20**. Upon expansion and deformation, the flaring portion is nonparallel to and at some angle slanting away from the longitudinal axis **26** of the ostial stent **20**. In addition, upon deformation or flaring out, the flaring portion deforms to varying degrees along its length and substantially conforms to the ostium **30** to the diseased portion **31** of the bifurcated vessel **21** (see FIG. **6**).

Radiopaque markers **35** (FIGS. **1**, **2**, **3**, and **6**) may be formed in or attached to the ostial stent **20** and their location may be selected to facilitate placement of the ostial stent **20** within a diseased bifurcated vessel **21**. The radiopaque markers **35** may be located near the joining line **36** between the tubular body and flaring portion and may also be aligned with the pedals **27** comprising the flaring portion. Since the radiopaque markers **35** may be observed through the use of radiography, strategic arrangement of the radiopaque markers **35** upon or within the ostial stent **20** allows the placement of the joining line **36** between the tubular body **24** and the flaring portion **25** at or near the ostium **30** to the diseased portion **31** of a bifurcated vessel **21**.

Advancement of the ostial stent **20** to the diseased portion **31** of the bifurcated vessel **21** is accomplished through the utilization of a balloon catheter **23**. The balloon catheter **23** contemplated comprises the structure and features that are typical to balloon catheters found in the art. The dimensional characteristics and material of the balloon catheter **23** utilized for the advancement of the ostial stent **20** is dependent upon the application. In general, the balloon catheter **23** embodies a balloon portion **37** and a hollow, tubular member **38** extending proximally therefrom. The tubular member **38** is in fluid communication with the balloon portion **37** and thereby enables the balloon **37** with expansion and deflation capabilities. The tubular member **38** is also comprised of sufficient rigidity so that the advancement of the balloon catheter **23** and ostial stent **20** through the patient's vasculature is possible. In addition, the tubular member may embody a secondary cavity through which a guidewire (not shown) may be placed.

The balloon catheter **23** is of sufficient length to enable the delivery of the ostial stent **20** to the area of the diseased bifurcated vessel **21** and the balloon **37** of the balloon catheter **23** is capable of securely holding the ostial stent **20** during advancement and capable of expanding sufficiently to seat and cap the ostial stent **20** within the diseased vessel **21**. First, the balloon catheter **22** is loaded with an unexpanded and undeformed ostial stent **20** and then entered into the patient's circulatory system through a cutdown **38**. Therefore, advancement of the ostial stent **20** is achieved by applying force **40** to a portion of the tubular member **38** extending outside the patient's body.

By way of example, the ostial stent **20** is shown loaded upon the balloon catheter **23** with the flaring portion **25** at the distal end of the balloon catheter **23**. It is contemplated, however, that the ostial stent **20** may be loaded with the tubular body **24** at the distal end of the balloon catheter **23** (not shown).

Through the use of radiography, the strategically positioned radiopaque markers **35** are viewed, and the ostial

stent is positioned within the diseased portion **31** of a bifurcated vessel **21** (FIG. 6). Thereafter, balloon catheter **23** is expanded, and the tubular body **24** is seated within and repairs the diseased vessel **21** and the flaring portion **25** is expanded and deformed so that the ostial stent **10** "caps" the ostium to the diseased portion **31** of the vessel **21**. Where the ostial stent **20** properly "caps" the ostium **30** to the diseased portion of the bifurcated vessel **21**, the flaring portion **25** substantially conforms to the vessel walls **41** comprising the bifurcation **22**, thereby allowing for unobstructed flow of blood through the bifurcated vessel. Although the seating of the tubular body **24** and "capping" of the flaring portion **25** may be accomplished contemporaneously, it may be preferred that one follow the other. Additionally, in order to properly repair the diseased vessel, the length of the tubular body **24** is selected so that the entire diseased portion **31** extending away from the ostium **30** is repaired and the length of the flaring portion **25** is selected so that it repairs, upon deformation, the entire diseased area **31** at the ostium **30** to the bifurcation **22**.

It is also contemplated that expansion and deformation of the ostial stent **20** can be accomplished through the use of a series of various sized and shaped balloons or by means of bi-balloon **42** or tri-balloon **43** catheter structures where the various sections of the balloon catheter act to carry the ostial stent **20**, seat the tubular body **24** and deform the flaring portion (FIGS. **7** and **8**). Irrespective of the mechanism employed, it is the seating within and "capping" of the ostium **30** to the diseased portion **31** of the bifurcated vessel **21** that must be achieved.

Once the ostial stent **20** is properly seated and "capped" within the bifurcated vessel **21**, the diseased vessel **21** is completely repaired and blood is not obstructed in any portion of the bifurcation **22**. The balloon catheter **23** can then be removed through the cutdown **39**, and the cutdown **39** can be closed. Thereafter, the repair site is available for further interventional treatment should it be necessary.

In another embodiment, an ostial stent **44** (not shown) can be comprised of a memory-retaining material such as NiTi. At a cold temperature, the ostial stent **44** would be unexpanded and undeformed. At an increased temperature, the ostial stent **44** would have an expanded and deformed configuration. During transport, the cold temperature of the ostial stent **44** could be maintained. Upon arrival at the diseased area, the stent **44** could be subjected to an increased temperature and allow the ostial stent **44** to deform and expand, thereby capping and seating the ostial stent **44** within a bifurcation. The deformed and expanded configuration would be retained at normal body temperature.

Advancement of the memory-retaining ostial stent **44** is also contemplated to be accomplished by means of a balloon catheter. In order to maintain the unexpanded and undeformed shape configuration of the memory-retaining ostial stent **44**, the balloon catheter could provide means to maintain the cold temperature of the ostial stent **44**. One means contemplated is loading the balloon catheter carrying the memory-retaining ostial stent **44** with a compound having a cold temperature. The cold compound could then be removed and replaced with a high-temperature compound. The high-temperature compound would cause the memory-retaining ostial stent **44** to deform and expand, thereby seating within and capping a diseased vessel.

It is also contemplated that only a portion of the ostial stent **44** be comprised of a memory-retaining material. For this stent, balloon expansion can be utilized to expand or deform a portion of the stent that was not comprised of a memory-retaining material.

In another embodiment, an ostial stent **45** is comprised of spring-like material (FIG. **9**). Advancement of the spring-like ostial stent **45** is accomplished by a balloon catheter **46**. In this embodiment, a retaining sleeve **47** is employed to maintain the spring-like ostial stent **45** in its unexpanded and undeformed configuration. Upon arrival of the spring ostial stent **45** at the repair site, removal of the retaining sleeve **47** allows the spring-like ostial stent **45** to spring to its expanded and deformed configuration, thereby seating and "capping" a diseased vessel **21** at a bifurcation **27**.

It is also contemplated that only a portion of the spring ostial stent **45** be comprised of spring-like material. Thus, deformation or expansion of the portion that is not comprised of spring-like material can be accomplished by a balloon catheter.

From the foregoing, it will be appreciated that the ostial stent of the invention allows complete repair of a diseased vessel of a bifurcation and provides a method and apparatus for accomplishing the same. It will also be appreciated that proper seating and "capping" of the ostial stent **20** within a diseased, bifurcated vessel **21** achieves reparation without obstructing the flow of blood at the site of the bifurcation.

While several particular forms of the invention have been illustrated and described, it will also be apparent that various modifications can be made without departing from the spirit and scope of the invention. Thus, it should be understood that various changes in form, detail, and application of the present invention may be made without departing from the spirit and scope of this invention.

I claim:

**1**. An expandable stent comprising a tubular body having a pair of ends, and a flaring portion attached to one of said ends of said tubular body, said flaring portion being capable of flaring to an angle exceeding 90° relative a longitudinal axis extending through said stent, said stent having an undeployed configuration wherein said tubular body and said flaring portion are unexpanded and said flaring portion is parallel to said longitudinal axis and a deployed configuration, wherein said tubular body and said flaring portion are expanded and said flaring portion is flared relative to said longitudinal axis.

**2**. The expandable stent of claim **1**, wherein said flaring portion comprises a plurality of individual segments.

**3**. The expandable stent of claim **2**, wherein said flaring portion comprises a plurality of individual segments connected by a malleable material.

**4**. The expandable stent of claim **1**, including means for expanding said tubular body and said flaring portion and flaring said flaring portion from said undeployed configuration to said deployed configuration.

**5**. The expandable stent of claim **4**, wherein said stent is constructed of a memory-retaining material and said means for expanding said tubular body and said flaring portion and flaring said flaring portion comprises said memory-retaining material.

**6**. The expandable stent of claim **5**, wherein said memory-retaining material retains said undeployed configuration at a cold temperature.

**7**. The expandable stent of claim **5**, wherein an increase in temperature, causes said tubular body and flaring portion to expand and said flaring portion to flare from said undeployed configuration to said deployed configuration.

**8**. The expandable stent of claim **4**, wherein said stent is constructed of a spring-like material and said means for expanding said expandable stent and flaring said flaring portion comprises said spring-like material.

9. The expandable stent of claim 8, wherein said spring-like material of said stent is biased radially outwardly wherein said stent maintains an unexpanded configuration under a retaining force.

10. The expandable stent of claim 8, wherein said spring-like material expands said stent radially outwardly so that said stent assumes an expanded configuration in the absence of a retaining force.

11. The expandable stent of claim 4, wherein said flaring portion of said stent is comprised of a spring-like material.

12. The expandable stent of claim 11, wherein said flaring portion of said stent is biases towards being flared relative said longitudinal axis wherein said flaring portion of said stent maintains an unflared configuration in the presence of a retaining force.

13. The expandable stent of claim 11, wherein said spring-like material causes said flaring portion of said stent to flare such that said flaring portion assumes a flared configuration in the absence of a retaining force.

* * * * *

# United States Patent [19]

**Bout n et al.**

[11] **Patent Number: 4,964,850**

[45] **Date of Patent: Oct. 23, 1990**


[54] **METHOD FOR TREATING TRANS-NASAL SINUS AFFLICTIONS USING A DOUBLE T-SHAPED TRANS-NASAL AERATOR**


[76] Inventors: **Vincent Bouton; Corine Bouton, both of 390 Avenue de Général Leclerc, Damarie Les Lys, France**



[21] Appl. No.: **361,729**

[22] Filed: **Jun. 2, 1989**

**Related U.S. Application Data**

[63] Continuation of Ser. No. 116,451, Nov. 3, 1987, abandoned.

[51] **Int. Cl.**[5] ..... **A61M 31/00**

[52] **U.S. Cl.** ..... **604/54; 604/8; 604/106; 606/108**

[58] **Field of Search** ..... 604/283, 280, 281, 194, 604/8, 10, 49, 250, 48, 51, 54, 106, 156, 264; 128/305; 606/198, 199



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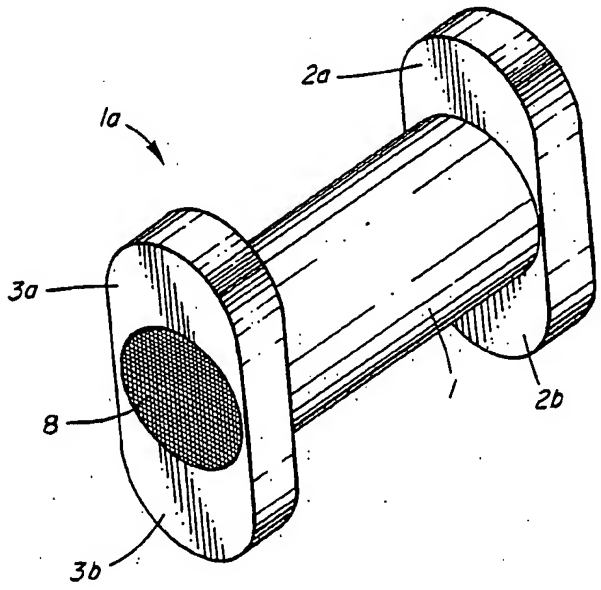
*Primary Examiner*—C. Fred Rosenbaum
*Assistant Examiner*—Katheen H Daley
*Attorney, Agent, or Firm*—Lorusso & Loud



[57] **ABSTRACT**

A method for using a surgical apparatus that permits invisible and permanent drainage and aeration of chronically affected sinus passages in children and adults is disclosed. The apparatus is made of flexible plastic material, preferably of silicon or polyethylene. T-shaped wings located at the two extremities of a tube permit the apparatus to be held in position after insertion and to be with- drawn by means of pliers. The size of the aerator, its length and its wings can vary according to the age of the patient, the respective illness and the requirements of endoscopic control. Positioning of the aerator is accomplished by means of a delivery device in which the aerator is inserted with its wings folded. The aerator is pushed by means of a mandrel into the sinus up to a stop, whereupon the internal wings deploy; at this point it is necessary only to withdraw the delivery device to have the aerator in place.


**6 Claims, 4 Drawing Sheets**



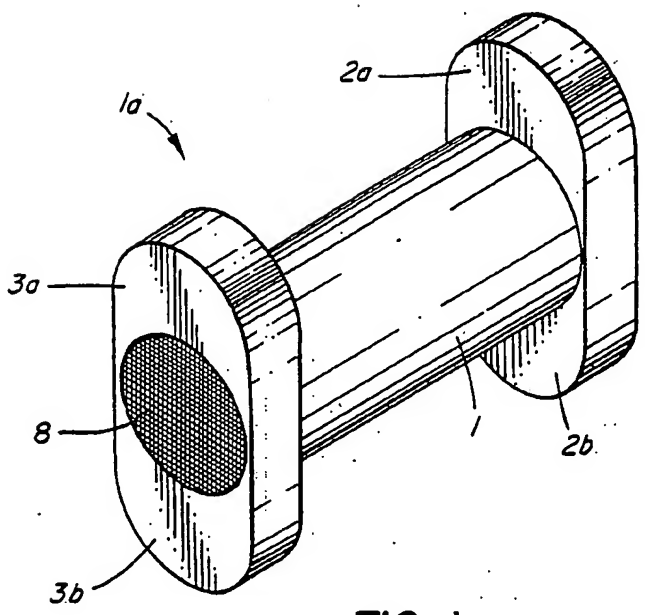



FIG. 1

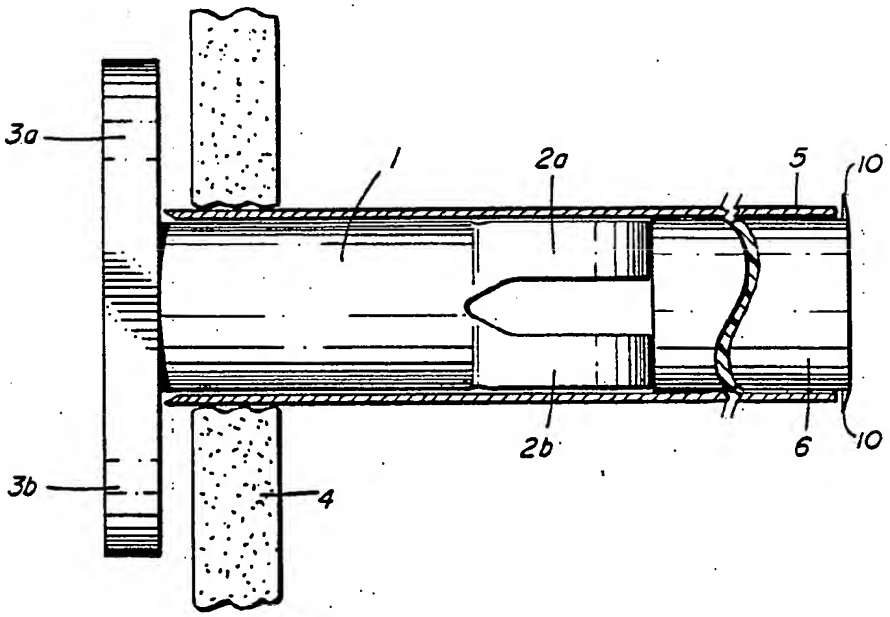
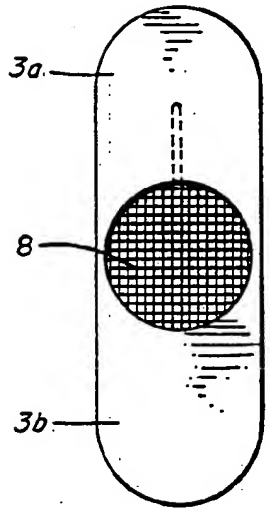



FIG. 2

FIG. 3



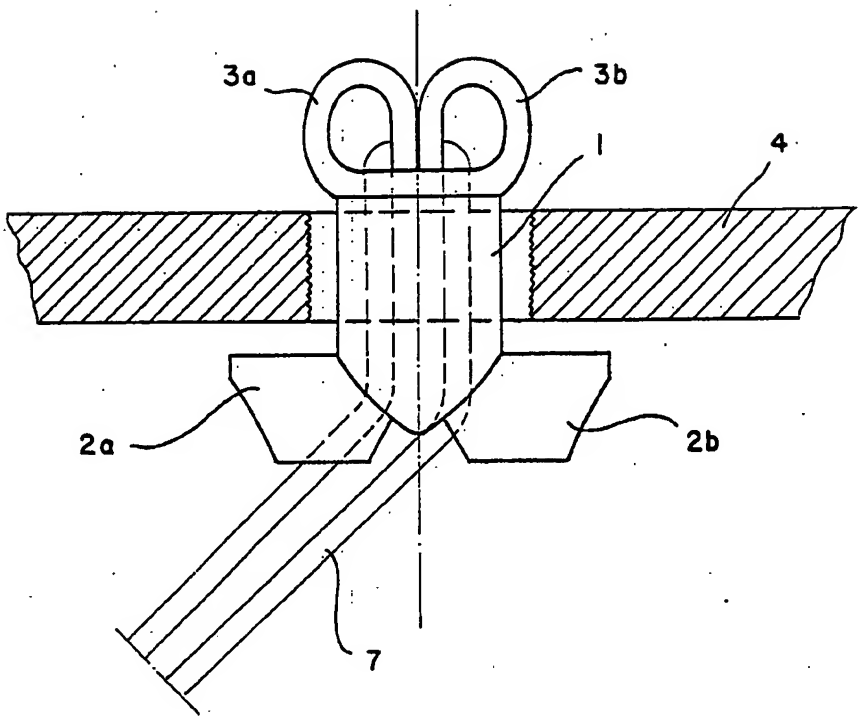



FIG. 4

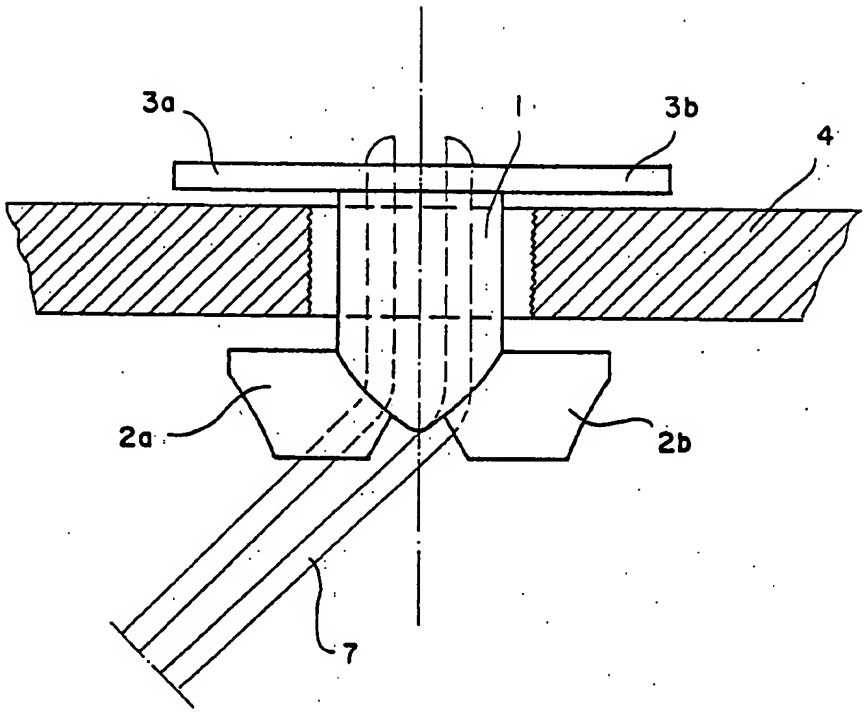



FIG. 5

# METHOD FOR TREATING TRANS-NASAL SINUS AFFLICTIONS USING A DOUBLE T-SHAPED TRANS-NASAL AERATOR

This is a continuation f co-pending application Ser. No. 07/116,451 now abandoned filed on Nov. 3, 1987.

## BACKGROUND OF THE INVENTION

The present invention relates to a surgical device that permits the permanent and invisible drainage and/or aeration of chronically or sub-acutely affected maxillary sinuses. The sinus is traditionally drained by means of a drain that exits from the narinary orifice. This allows the treatment for a period of from 7 to 15 days, but not on a permanent basis. It would be therefore desirable to provide a device allowing a permanent drainage of the sinus.

## SUMMARY OF THE INVENTION

In one aspect, the invention provides a sinal aerator for permanently and invisibly draining maxillary sinuses and ventilating the latter in patients suffering from subacute or chronic affections. The aerator is characterized in that it comprises a hollow drain-type tube of a flexible plastic material introduced into the sinus to be treated. The tube straddles the bony wall separating the sinal cavity and the nasal canal, thus permitting communication between the cavity and the canal.

In another aspect, the invention provides a device for positioning the sinal aerator characterized in that it comprises a delivery device inside which is disposed a mandrel that permits the aerator to be slid in the sinal cavity until the internal wings open.

The aerator is small and cannot be seen except during rhinological examinations which must be performed by a specialist. The aerator may be left in its position during the time required to treat the sinal illness, up to several months, if necessary. Its installation, which requires the use of both hands, presents no difficulty to trained personnel.

According to a preferred embodiment of the invention, the aerator allows the physician to monitor by endoscopic means the state of the treated sinus. In a preferred embodiment the sinal aerator is manufactured of silicon or polyethylene.

## BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is an enlarged perspective view of one preferred embodiment of the invention;

FIG. 2 is a cross-sectional view of one preferred delivery and positioning device;

FIG. 3 is an enlarged front view of one preferred embodiment of the invention;

FIG. 4 is a view of the aerator with another preferred positioning device, prior to the positioning;

FIG. 5 is a view corresponding to FIG. 4, after the positioning.

## DETAILED DESCRIPTION OF THE EMBODIMENTS

Referring to FIG. 1, the aerator comprises a hollow tube 1.5 mm in radius; 6 mm long and 0.5 mm thick. Two wings, 3*a* and 3*b*, are attached at one end of the tube. The wings are 1 mm thick and 3 mm long and open to an angle of 90°. When pressed against the internal face of the intersinuso-nasal wall 4 these wings produce a stopping effect which is responsible for holding the aerator in its installed position.

At the second end f the tube two identical wings, 2*a* and 2*b* are attached. These wings prevent the aerator from sliding into the sinus cavity, which might occur, for example, during bl wing. The longitudinal axis of these wings is then disposed along the horizontal axis of the inferior nasal meatus. The wings, 2*a* and 2*b*, situated in the nasal canal permit additionally localization of the aerator and, when required, its withdrawal with a pair of standard prehensile pliers.

Depending on a particular embodiment, the length and the diameter of the tube may be reduced or increased. An increased internal diameter of the tube permits introduction of an instrument of endoscopic control into the sinal cavity. Similarily, the number, length and thickness of the wings may be changed to suit the age of the person treated, particularities of the illness and personal preferences of the staff administering the treatment. The angle at which the wings are attached to the tube may vary, thus permitting the aerator to be inclined toward the rear. Such positioning simplifies the ventilation of the treated sinus by warm air expired through the nose.

An obturative membrane 8 impervious to water but permeable to air may close the tube at its nasal orifice. This embodiment permits bathing, swimming and other water activities.

Referring to FIG. 2, the positioning device of the invention consists of a delivery device 5 that permits the perforation of the bony wall 4 separating the sinus from the nasal canal, through which the operation takes place without sight control. This action is performed as a "sinus puncture" in the inferior nasal meatus. Prior to the positioning the aerator is placed by the operator inside the delivery device with the wings folded. The positioning device comprises a mandrel 6 disposed inside the delivery device 5 so as to permit the aerator to be slid forward until the internal wings deploy. A stopping device assures the operator advancing the mandrel that the sinus aerator is properly positioned and that any further advancement of the mandrel is undesirable. In this manner the aerator is prevented from being pushed too far and irretrievably lost in the sinus cavity. A fin-type device 10 stops the movement of the mandrel inside the delivery device at the moment when the fin meets the end of the slit designed to admit the internal wings and a portion of the aerator tube into the desired position. Once the internal wings have been deployed and the stop prohibits further progress, the operator withdraws the delivery device; the aerator is kept in position by the internal wings resting against the internal face of the bony wall; the delivery device slides along the aerator. When the latter is entirely freed, the external wings deploy.

According to another embodiment of the invention the positioning device comprises a bent pliers inserter 7 slid inside the tube 1 of the drain to grasp the internal wings 3*a* and 3*b* and keep them in the undeployed position (FIG. 4). The pliers-drain assembly is placed in the orifice created with the help of the delivery device 5, the external wings 2*a* and 2*b* of the drain helping to create a stop which limits the advance of the aerator during the operation. At this moment, the nasal canal is endoscopically examined, then the jaws of the pliers are opened, t permit the internal wings to deploy inside the sinus (FIG. 5). Subsequently, the jaws of the pliers are brought together to permit the withdrawal of the

pliers, which are then gently slid out f the drain which is held in place by the positi ning of the deployed internal wings. From this time, the device according to the invention is in place.

In any embodiment, the wings do not deploy due to any specific mechanism. Their final disposition results from the fact that they have been moulded in their respective positions and from the characteristics of the material used in their manufacture.

The embodiments of the invention in which an exclusive property or privilege is claimed are defined as follows:

1. A method for draining and ventilating maxillary sinuses in patients suffering from sub-acute or chronic affections, comprising the steps of:

perforating the bony wall separating a sinal cavity from a nasal passage to provide an opening in the bony wall;

providing a hollow drain tube made of flexible plastic material with flexible wings attached at each end, wherein said wings permit unidirectional passage of the tube through an opening to allow insertion of the hollow drain tube through the opening in the bony wall and to retard movement of the hollow drain tube once positioned in the bony wall;

inserting said hollow drain tube with positioning means until the wings on one end of said hollow drain tube pass through the perforated bony wall and into the sinal cavity;

deploying wings on the end within the sinal cavity thereby locking said hollow drain tube on the sinal cavity side on said bony wall; and

withdrawing the positioning means from the bony wall, said withdrawing liberating the wings in an open position to lock the hollow drain tube in place on the nasal passage side of the bony wall and provide a fixed draining and ventilating means between the sinal cavity and nasal cavity.

2. A method according to claim 1 further comprising the step of closing the wings on one end of the hollow drain tube before inserting said hollow drain tube through the opening in the bony wall.

3. A method according to claim 2, wherein said wings remain closed until said positioning means is removed from the bony wall, causing the wings on each end to open and lock the hollow drain tube in place.

4. A method according to claim 2, wherein said hollow drain tube is inserted through a temporary drain tube positioning device to the point at which the wings at one end of the hollow drain tube pass beyond the temporary drain tube positioning device and open.

5. A method according to claim 1 wherein said hollow drain tube is inserted into said opening in the bony wall with bent pliers which extend through the hollow drain tube and grasp the wings at one end to hold them in a compressed state.

6. A method for draining and ventilating maxillary sinuses in patients suffering from sub-acute or chronic affections, comprising the steps of:

perforating the bony wall separating a sinal cavity from a nasal passage to provide an opening in the bony wall;

providing a hollow drain tube made of flexible plastic material with flexible wings attached at each end, wherein said wings permit unidirectional passage of the tube through an opening to allow insertion of the hollow drain tube through the opening in the bony wall and to retard movement of the hollow drain tube once positioned in the bony wall;

closing the wings on one end of the hollow drain tube by compressing the wings with bent pliers before inserting said hollow drain tube through the opening in the bony wall;

inserting said hollow drain tube with said bent pliers wherein said wings remain closed until the wings on one end of said hollow drain tube pass through the perforated bony wall and into the sinal cavity;

deploying wings on the end within the sinal cavity thereby locking said hollow drain tube on the sinal cavity side on said bony wall; and

withdrawing the bent pliers from the bony wall, said withdrawing liberating the wings in an open position to lock the hollow drain tube in place on the nasal passage side of the bony wall and provide a fixed draining and ventilating means between the sinal cavity and nasal canal.

* * * * *

US005456714A

# United States Patent [19]

Owen

[11] Patent Number: 5,456,714

[45] Date of Patent: Oct. 10, 1995

[54] **TUBULAR SURGICAL IMPLANT HAVING A LOCKING RING AND FLANGE**

[76] Inventor: **Earl R. Owen**, Microsurgery Centre, 1 Esther Street, Surry Hills, NSW 2010, Australia

[21] Appl. No.: **170,312**

[22] PCT Filed: **Jul. 3, 1992**

[86] PCT No.: **PCT/AU92/00328**

§ 371 Date: **Jan. 3, 1994**

§ 102(e) Date: **Jan. 3, 1994**

[87] PCT Pub. No.: **WO93/00868**

PCT Pub. Date: **Jan. 21, 1993**

[30] **Foreign Application Priority Data**

Jul. 4, 1991 [AU] Australia ..... PK7057

[51] **Int. Cl.**[6] ..... **A61F 2/06**

[52] **U.S. Cl.** ..... **623/1**; 623/12; 604/8; 606/151; 606/153

[58] **Field of Search** ..... 623/1, 12; 604/8; 606/151, 153

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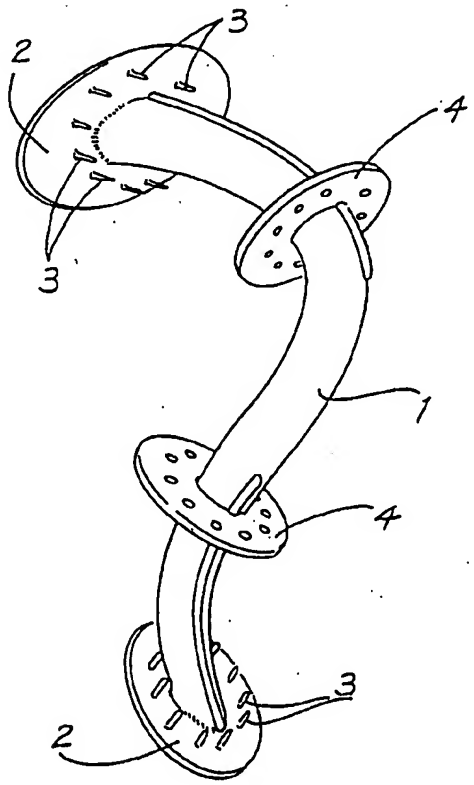
*Primary Examiner*—Paul B. Prebilic

*Attorney, Agent, or Firm*—Ostrolenk, Faber, Gerb & Soffen

[57] **ABSTRACT**

A tubular surgical implant for joining to a wall of a vessel or hollow organ is disclosed such that the implant opens into the interior of the vessel or organ. The implant has an open ended tube, a deformable flange at one end of the tube, a plurality of spikes extending from the flange, alongside and generally parallel to the tube, and a locking ring arranged to slide axially on the tube, the locking ring incorporating a plurality of holes aligned with and adapted to received the spikes.

**10 Claims, 3 Drawing Sheets**



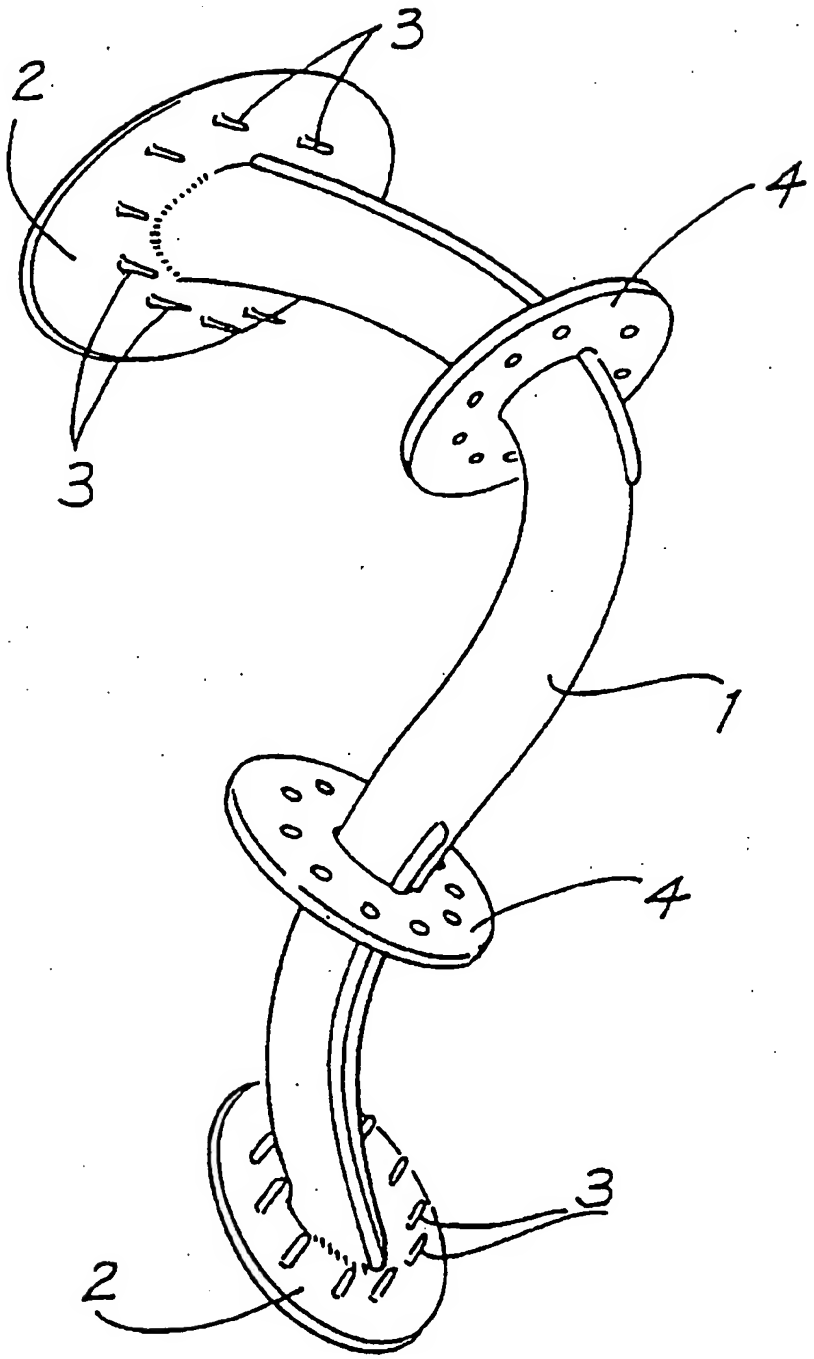



FIG. 1

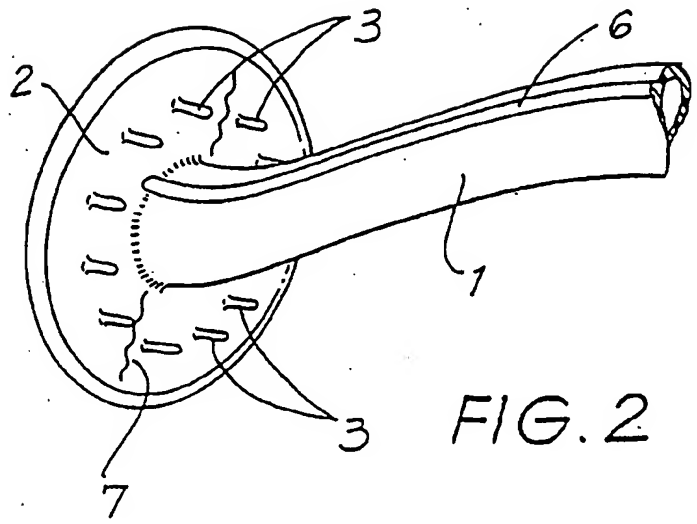



FIG. 2

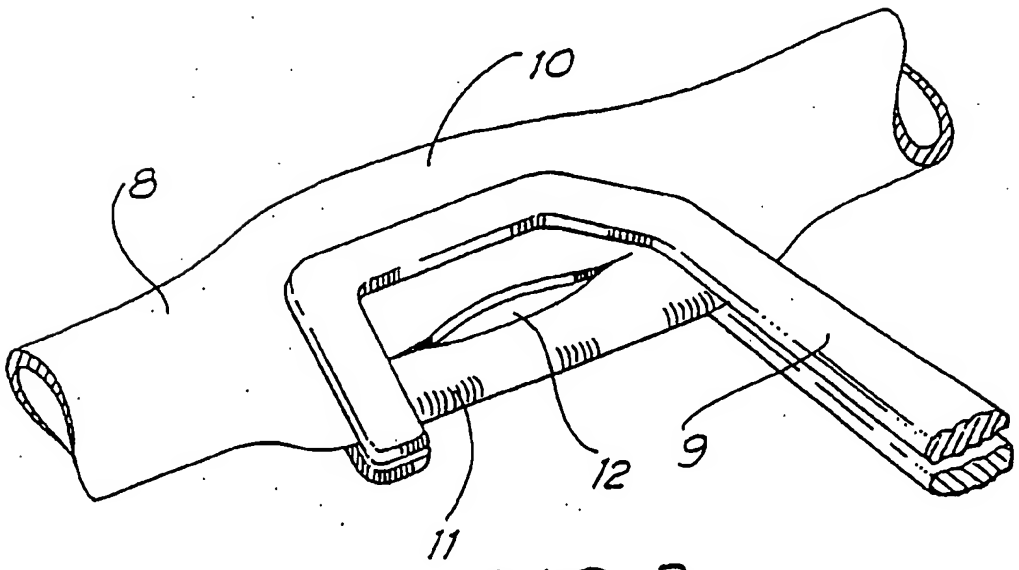



FIG. 3

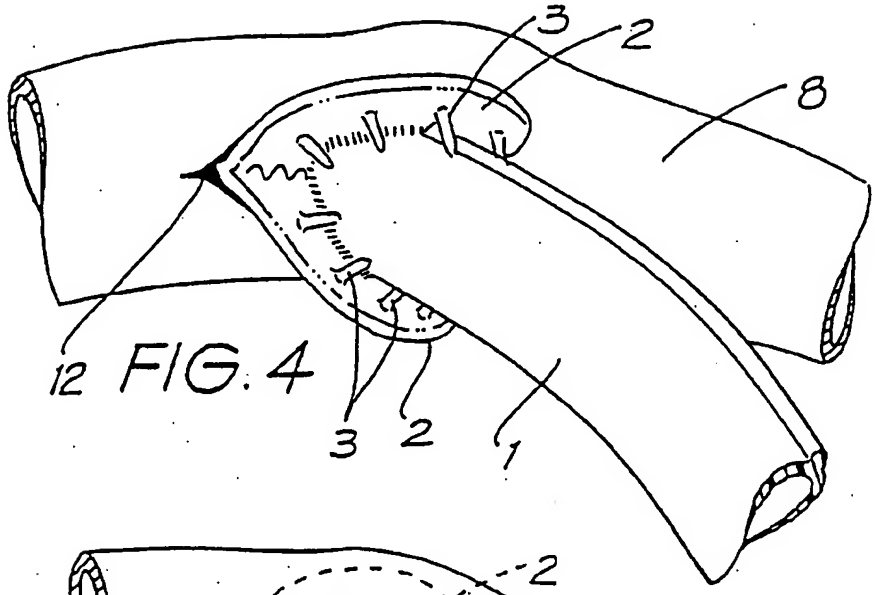



FIG. 4

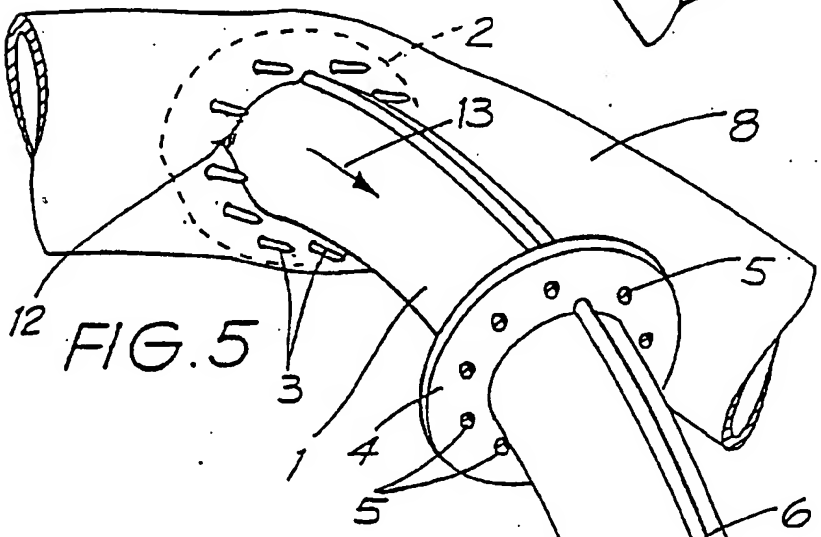



FIG. 5

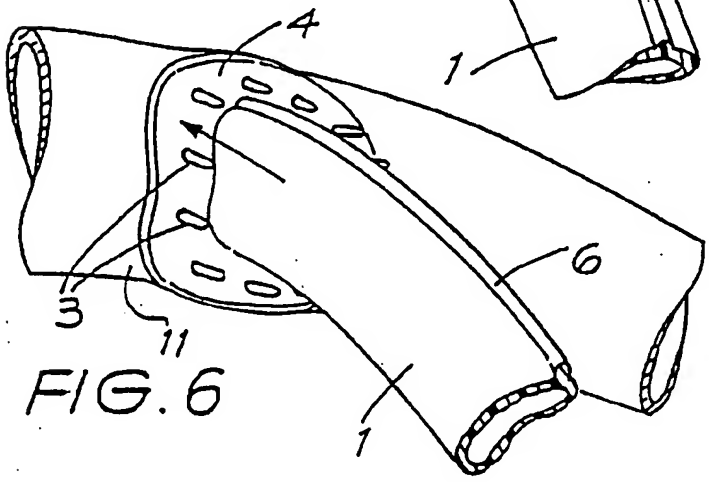



FIG. 6

# TUBULAR SURGICAL IMPLANT HAVING A LOCKING RING AND FLANGE

## TECHNICAL FIELD

This invention relates to a tubular surgical implant and has been devised particularly though not solely for use as a by-pass device and specifically as a coronary by-pass device.

## BACKGROUND ART

So-called "heart by-pass" surgery is relatively common and is necessitated by blockage or partial blockage and narrowing of the coronary arteries causing ischaemia or a lack of blood supply to the heart muscle, distally. The pain felt as a result is known as angina and the result can be heart attack, death or recovery with damage to the heart muscle. The present treatment by way of heart by-pass surgery is effective but is expensive to carry cut, time consuming, and requires stopping the heart and placing the patient on a life-support artificial heart lung machine using large quantities of blood. Surgeons must then harvest leg veins or cheer arteries or both to sew into position as a by-pass from the aorta to the distal coronary artery.

It is desirable to provide a much less complicated procedure for carrying out a by-pass operation, which is not only faster and lean expensive to perform, but also results in less risk to the patient.

## DISCLOSURE OF THE INVENTION

The present invention therefore provides a tubular surgical implant adapted to be joined to a wall of a vessel or hollow organ such that the implant opens into the interior of the vessel or organ, said implant comprising an open ended tube, a deformable flange at one end of the tube, a plurality of spikes extending from the flange, alongside and generally parallel to the tube, and a locking ring arranged to slide axially on the tube, the locking ring incorporating a plurality of holes aligned with and adapted to receive the spikes.

Preferably the locking ring is keyed to the tube, preventing rotation of the ring relative to the tube,

Preferably the spokes and the holes in the locking ring are provided with a locking mechanism arranged to retain the spikes within the holes when the locking ring is engaged with the spikes.

The flange may be deformable relative to the tube such that the flange may be deformed to lie against the tube for insertion into an opening in the wall of the vessel or organ.

Alternatively the flange may be deformable across one or more hinge lines in the flange, allowing parts of the flange to bend back against the tube for insertion into an open in the wall of the vessel or organ.

In one form of the invention the implant is adapted to connect two vessels or hollow organs and is provided with a flange and locking ring at both ends of the tube.

Preferably the tube and the flange are made of a plastics mesh which allows for incorporation of human tissue.

In a further aspect the invention provides a method of connecting two vessels or hollow organs by way of a surgical implant, comprising the steps of: providing a tubular surgical implant adapted to be joined to a wall of a vessel or organ such that the implant opens into the interior of the vessel or organ, said implant comprising an open ended tube, a deformable flange at one end of the tube, a plurality of spikes extending from the flange, alongside and generally parallel to the tube, and a locking ring arranged to slide axially on the tube, the locking ring incorporating a plurality of holes aligned with and adapted to receive the spikes; cutting a hole or slit in the tissue wall of the first vessel or organ, inserting the end of the tube into the hole or slit with the flange deformed, allowing or causing the flange to open behind the tissue wall, engaging the spikes through the tissue wall and sliding the locking ring on the tube until the spikes are engaged with the holes in the locking ring.



## BRIEF DESCRIPTION OF DRAWINGS

Notwithstanding any other forms that may fall within its scope, one preferred form of the invention will now be described by way of example only with reference to the accompanying drawings, in which:

FIG. 1 is a diagrammatic perspective view of a tubular surgical implant according to the invention;

FIG. 2 is a detailed view of one end of the implant shown in FIG. 1;

FIG. 3 is a diagrammatic view of a blood vessel clamped and cut preparatory to engagement with the tubular surgical implant shown in FIG. 1;

FIG. 4 is a diagrammatic perspective view of the implant being inserted into the incision in the vessel;

FIG. 5 is a similar view to FIG. 4 showing the spikes of the implant being engaged; and

FIG. 6 is a similar view to FIGS. 4 and 5 showing engagement of the locking ring.

## MODES FOR CARRYING OUT THE INVENTION

In the preferred form of the invention a tubular surgical implant is provided for use as a by-pass between the aorta and a coronary artery although it will be appreciated that the device may be used in many other applications wherever it is necessary to join an artificial tube with a vessel or organ or to provide a by-pass between different vessels and/or organs. The implant is described as a double-ended device although it will be appreciated that in some applications the engagement flange and locking ring may be provided on one end of the tube only.

The implant comprises a tube (1) having a flange (2) at either end of the tube. The tube and flange may be formed from any suitable materials but are typically of a plastics mesh material such as a grade of GORTEX, an expanded polytetrafluoroethylene (Registered Trade Mark W.L. Gore & Associates, Inc., Newark, Del.) material which allows incorporation of human tissue and a long life for the device in the body.

Each flange is provided with a plurality of spikes (3) extending from the flange, alongside and generally parallel to the tube (1). In this sense the spikes face away from the open end of the tube.

The implant is further provided with locking rings (4) as the same general size and configuration of the flanges (2), the locking rings being arranged to slide axially on the tube (1). Each locking ring incorporates a plurality of holes (5) (FIG. 5) aligned with and adapted to receive the spikes (3) protruding from the corresponding flange (2).

In order to ensure alignment of the holes (5) with the spikes (3) the locking ring may be keyed to the tube by way of a keyway (6) on the tube and a corresponding projection or aperture (not shown) in the locking ring (4), preventing

rotation of the ring relative to the tube. In this manner, the holes (5) can be accurately aligned with the spikes (3) enabling the ring to be engaged with the spikes as will be described further below.

The flange (2) is deformable relative to the tube (1) either by deforming the entire flange relative to the tube so that the flange may lie against the tube for insertion into an opening of a vessel or organ, or alternatively the flange maybe deformable across one or more hinge lines (7) (FIG. 2) allowing parts of the flange to bend back against the tube as shown in FIG. 4 for insertion into an opening in the wall of the vessel or organ.

The use of the implant will now be described with reference to a typical coronary by-pass operation where the implant is engaged between the aorta and the distal coronary artery.

Referring to FIG. 3 the aorta (8) is first partially clamped by way of a non-traumatic clamp (9) positioned partially across the aorta to allow the continuing flow of blood through unclamped portion (10). The clamped portion (11) of the aorta (8) may then be cut to form an incision (12) for engagement with the implant.

As shown in FIG. 4, the flange (2) may be deformed as previously described and inserted through the incision (12) until the entire flange is positioned within the aorta. The flange is then allowed or caused to open behind the tissue wall of the aorta to its original configuration and the tube pulled back in the direction of arrow (13) (FIG. 5) engaging the spikes (3) through the tissue wall (11).

The locking ring (4) is then slid down the tube until the spikes (3) are engaged with the holes (5) in the locking ring as shown in FIG. 6.

The spikes (3) and the holes (5) in the locking ring (4) are provided with a series of locking mechanisms arranged to retain the spikes within the holes when the locking ring is engaged with the spikes as shown in FIG. 6. This locking mechanism may take any suitable configuration but is typically a series of "click into place" type of mechanisms which engages the locking ring at various spacings from the flange to allow for several aortic wall thicknesses.

The procedure may then be repeated at the other end of the implant to engage the other flange with the coronary artery, effectively and quickly providing a by-pass between the aorta and the coronary artery.

In the particular application of a heart by-pass operation the flange adapted to be engaged with the coronary artery may be smaller than the flange to be engaged with the aorta to suit the size of the vessel with which it is engaged. A range of different sized and ended device would be used to cover the range expected in different sized diameters and thicknesses of aortas and coronary arteries. In situations where there is more than one blockage in the coronary artery, the tubular surgical implant can be constructed as a manifold with one larger aortic proximal end and several separate coronary distal ends. The tubes may be either parallel sided or tapered (conical) as required for the desized flow rates.

In this manner a surgical implant is provided which enables a coronary by-pass operation to be performed without stopping the heart function or the aorta blood flow to the body and which furthermore does not entail the stripping of veins or arteries from other parts of the body to use as a by-pass conduit.

The implant has application in many other areas presently the province of vascular and microsurgery and may be used wherever it is necessary to join a tube to a vessel or hollow organ or to form a connection between two vessels and/or organs.

I claim:

1. A tubular surgical implant adapted to be joined to a wall of a vessel or hollow organ such that the implant opens into the interior of the vessel or organ, said implant comprising:

an open-ended tube having a distal end and a proximal end,

a deformable flange formed at the distal end of the tube for insertion through an opening in the wall of the vessel or hollow organ,

a plurality of spikes extending from the flange toward the proximal end of the tube, alongside and generally parallel to the tube, and

a locking ring arranged to slide axially on the tube in a direction from the proximal end of the tube toward the distal end of the tube, the locking ring incorporating a plurality of holes aligned with and adapted to receive the spikes.

2. A tubular surgical implant as claimed in claim 1 wherein the locking ring is keyed to the tube, preventing rotation of the ring relative to the tube.

3. A tubular surgical implant as claimed in claim 1 wherein the spikes and the holes in the locking ring are provided with a locking mechanism arranged to retain the spikes within the holes when the locking ring is engaged with the spikes.

4. A tubular surgical implant as claimed in claim 1 wherein the flange is deformable relative to the tube such that the flange may be deformed to lie against the tube for insertion into an opening in the wall of the vessel or organ.

5. A tubular surgical implant as claimed in claim 1 wherein the flange is deformable across one or more hinge lined in the flange, allowing parts of the flange to bend back against the tube for insertion into an opening in the wall of the vessel or organ.

6. A tubular surgical implant as claimed in claim 1 wherein the implant is adapted to connect two vessels or hollow organs and is provided with a flange and locking ring at both ends of the tube.

7. A tubular surgical implant as claimed in claim 1 wherein the tube and the flange are made of a plastics mesh which allows for incorporation of human tissue.

8. A method of connecting first and second vessels, or first and second hollow organs, or a first vessel and a second hollow organ, by way of a surgical implant, the method comprising the steps of:

providing a tubular surgical implant adapted to be joined to a tissue wall of a vessel or organ such that the implant opens into the interior of the vessel or organ, the implant comprising an open-ended tube, a deformable flange at one end of the tube, a plurality of spikes extending from the flange, alongside and generally parallel to the tube, and a locking ring arranged to slide axially on the tube, and the locking ring incorporating a plurality of holes aligned with and adapted to receive the spikes;

cutting an opening in the tissue wall of the first vessel or first organ;

inserting the end of the tube into the opening with the flange deformed;

allowing or causing the flange to open behind the tissue wall;

engaging the spikes through the tissue wall; and

sliding the locking ring on the tube until the spikes are

engaged with the holes in the locking ring.

9. A method as claimed in claim 8 wherein the area of the first vessel or the first organ surrounding the opening is isolated from the remainder of the first vessel or the first organ by way of a clamp before making the opening, in a manner allowing fluid to continue to flow through the remainder of the vessel or organ.

10. A method as claimed in claim 8 wherein the first vessel or the first organ comprises an aorta and the second vessel or the second organ comprises a distal coronary artery.

* * * * *

US005755735A

# United States Patent [19]

Richter et al.

[11] Patent Number: 5,755,735

[45] Date of Patent: May 26, 1998

[54] **BIFURCATED STENT AND METHOD OF MAKING SAME**

[75] Inventors: **Jacob Richter**, Tel Aviv; **Gregory Pinchasik**, Ramat Hasharon, both of Israel

[73] Assignee: **Medinol Ltd.**, Tel Aviv, Israel

[21] Appl. No.: **841,702**

[22] Filed: **Apr. 30, 1997**

**Related U.S. Application Data**

[62] Division of Ser. No. 642,297, May 3, 1996.

[51] **Int. Cl.**[6] ..... **A61M 29/00**

[52] **U.S. Cl.** ..... **606/194**; 128/898

[58] **Field of Search** ..... 128/898; 606/194, 606/198, 191, 195; 623/1, 12

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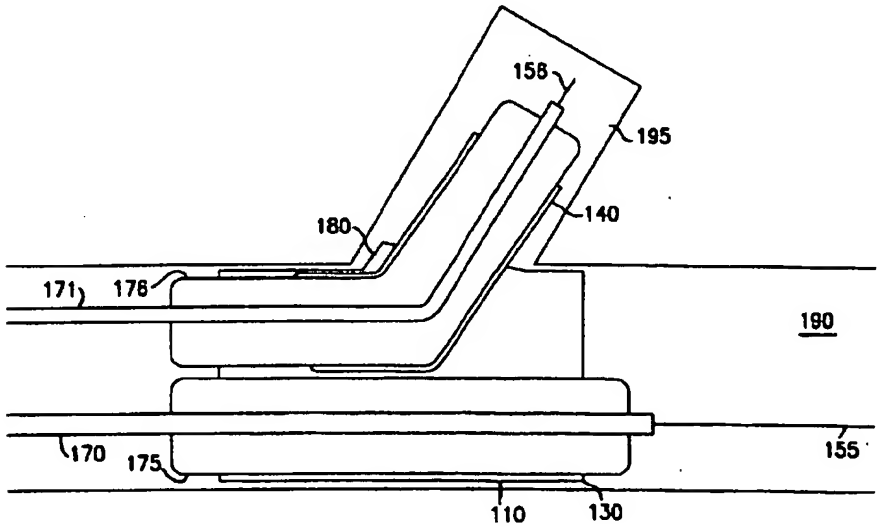
*Primary Examiner*—Michael Buiz
*Assistant Examiner*—Kevin Truong
*Attorney, Agent, or Firm*—Kenyon & Kenyon

[57] **ABSTRACT**

A bifurcated stent for insertion into a bifurcated vessel such as a blood vessel. In one embodiment, a first sheet is formed into a first leg, a second sheet is formed into a second leg, a third sheet is formed into a stem, and the two legs are attached to the stem. In a second embodiment, a first sheet is formed into a member having a first leg and half of a stem, a second sheet is formed into a second member having a second leg and half of a stem, and the two stem halves are combined to form the bifurcated stent. In a third embodiment, the stent comprises two sections that are serially inserted and assembled within the vessel at the site of the bifurcation to be treated.

**4 Claims, 15 Drawing Sheets**



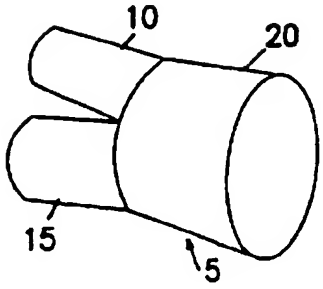



FIG. 1

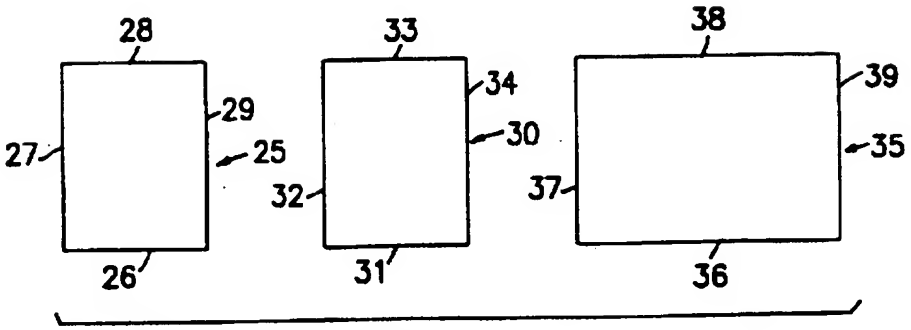



FIG. 2

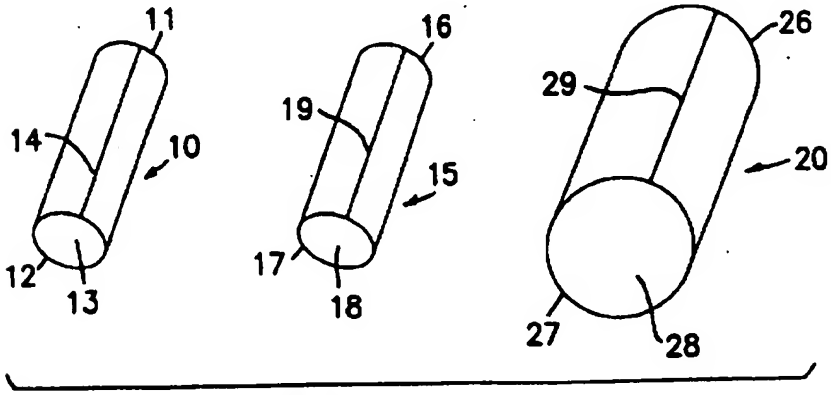



FIG. 3

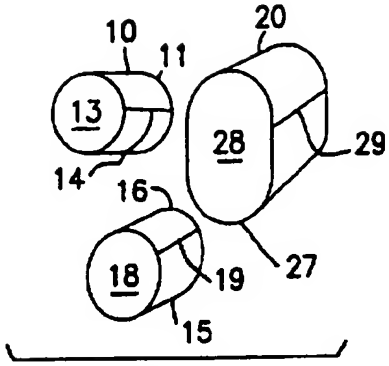



FIG. 4

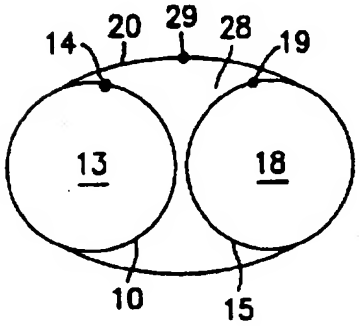



FIG. 5

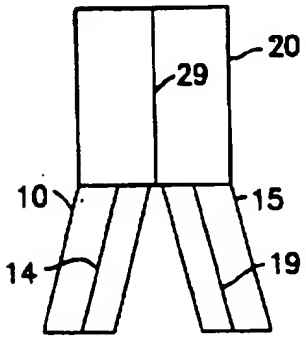



FIG. 6

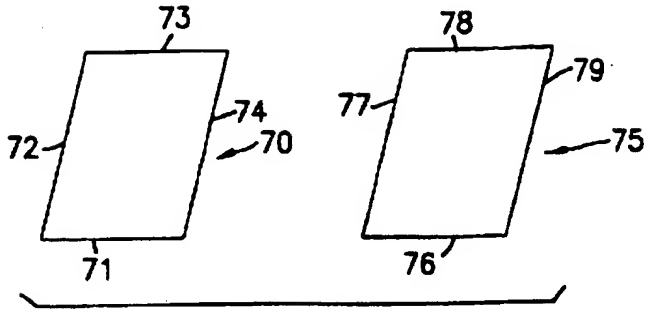



FIG. 7

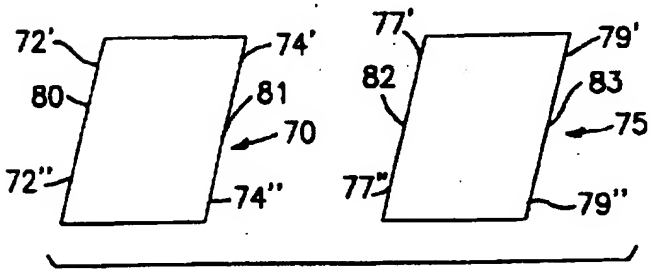



FIG. 8

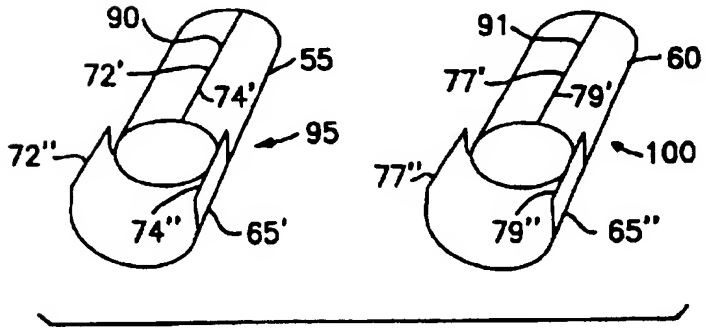



FIG. 9

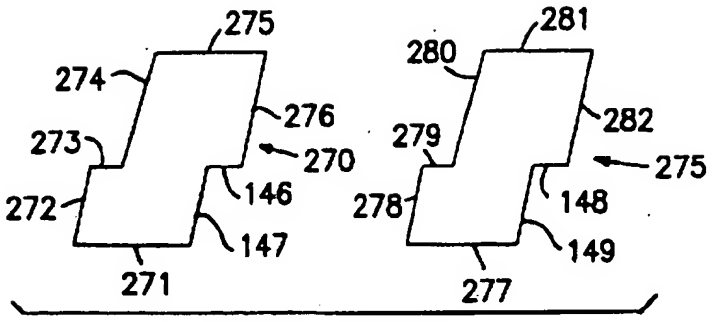



FIG. 7B

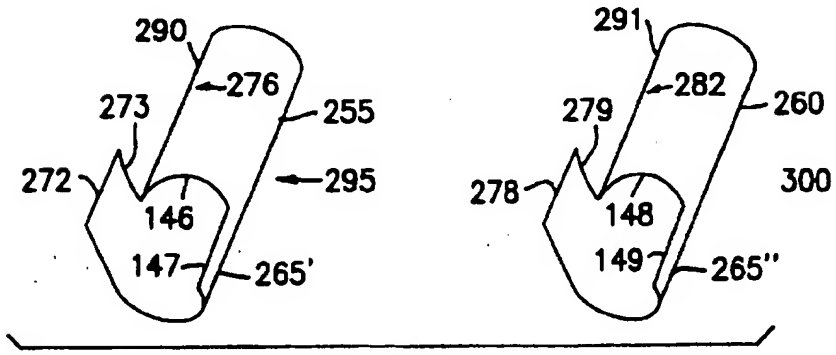



FIG. 9B

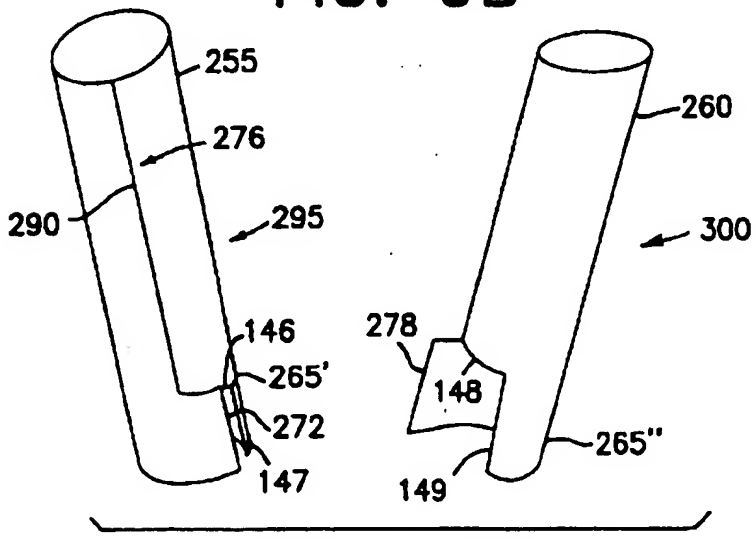



FIG. 10B

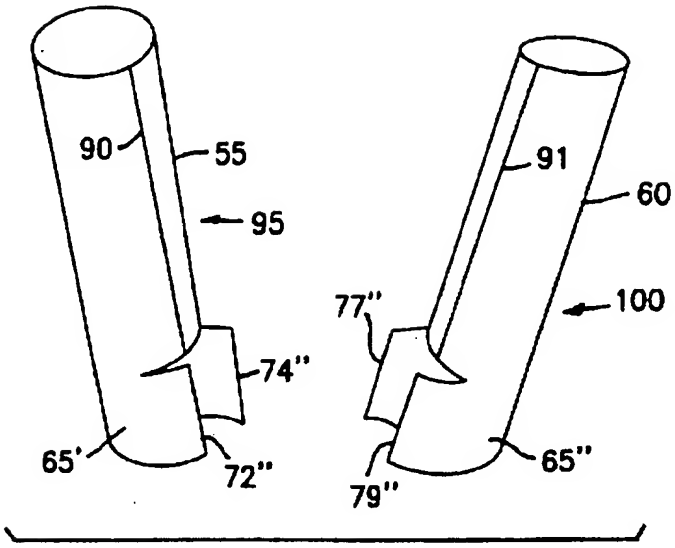



FIG. 10

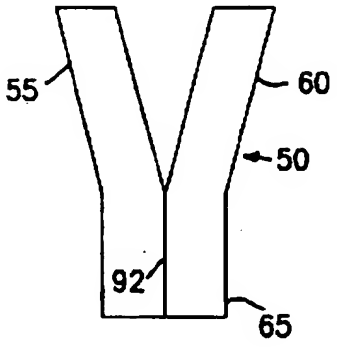



FIG. 11

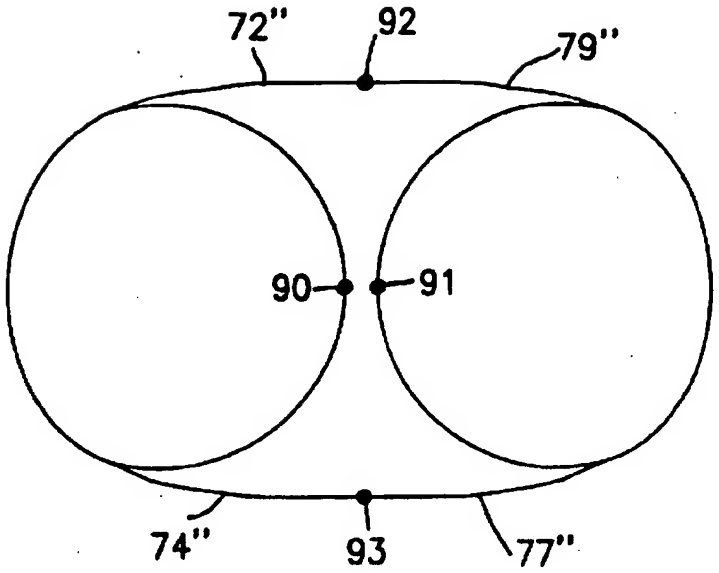



FIG. 12

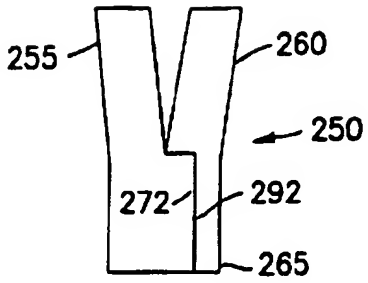



FIG. 11B

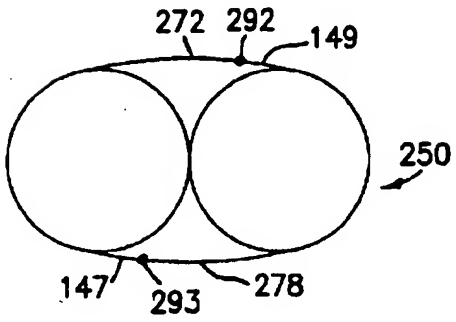



FIG. 12B

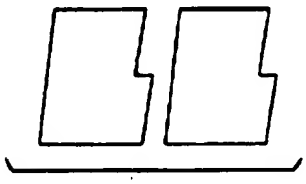


FIG. 12C

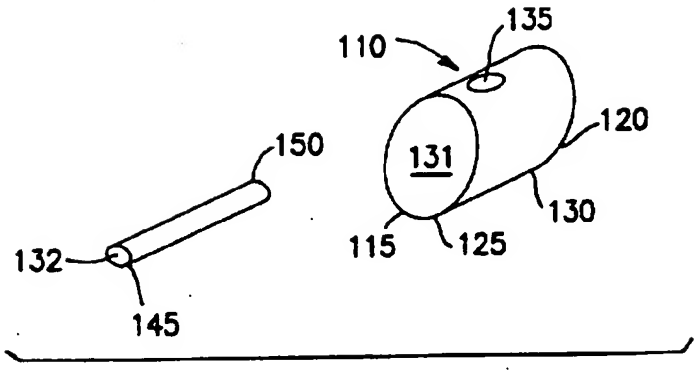



FIG. 13

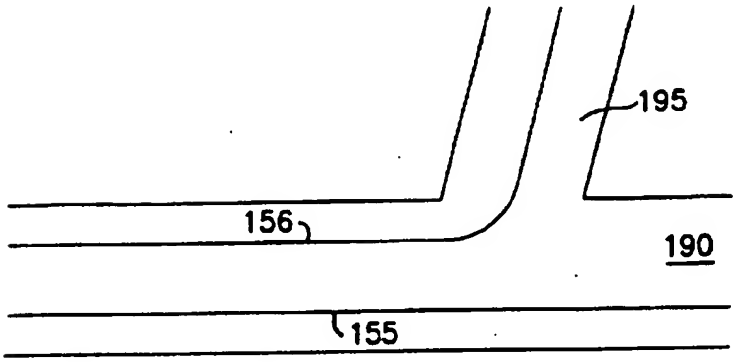



FIG. 14

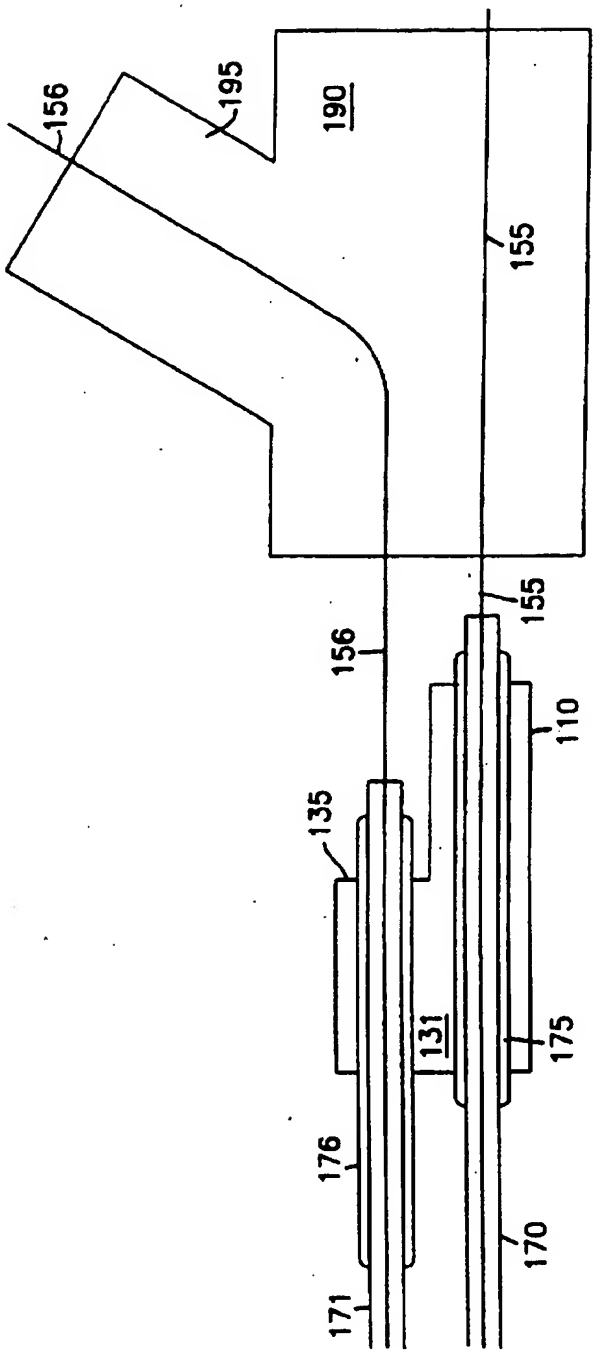



FIG. 15

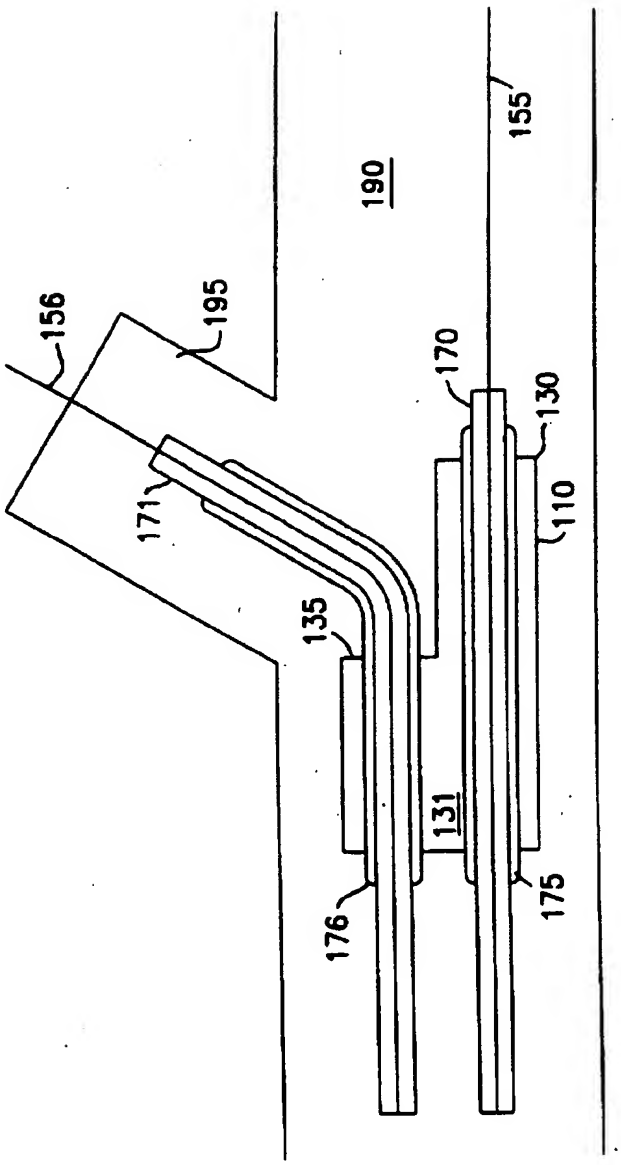



FIG. 16

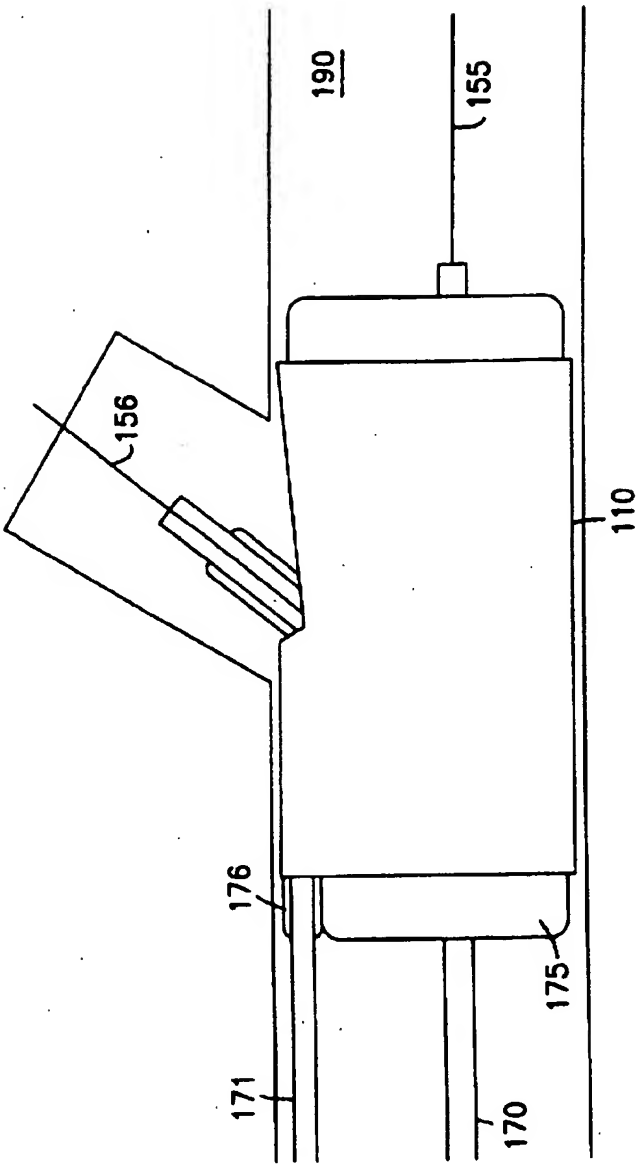



FIG. 17

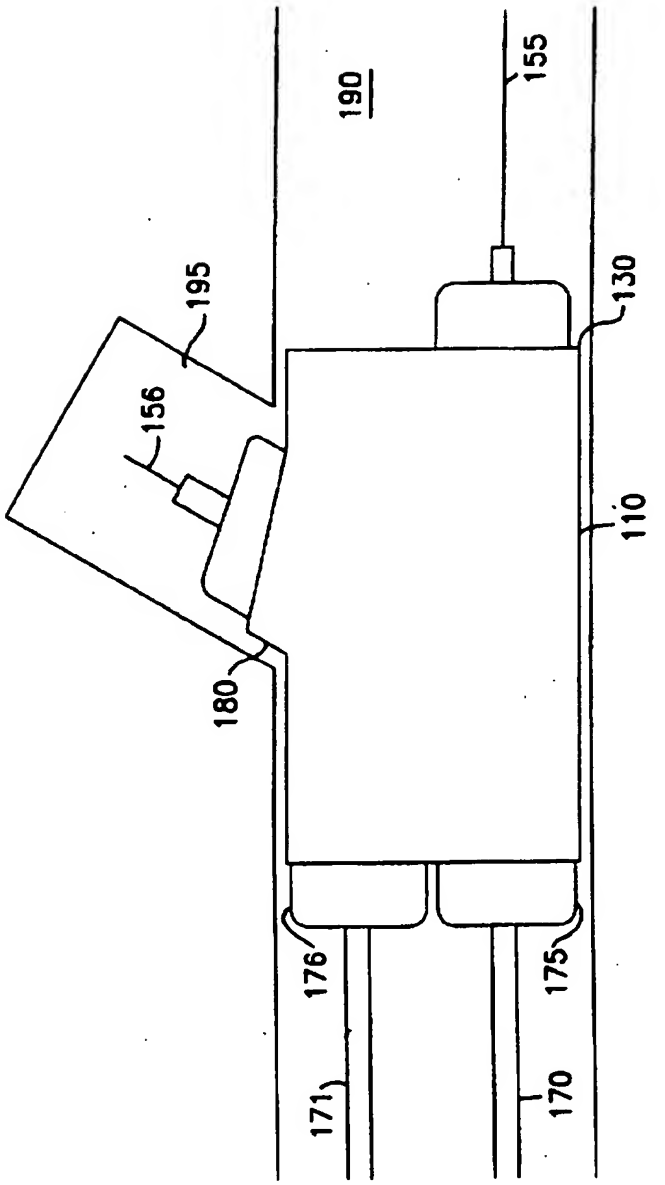



FIG. 18

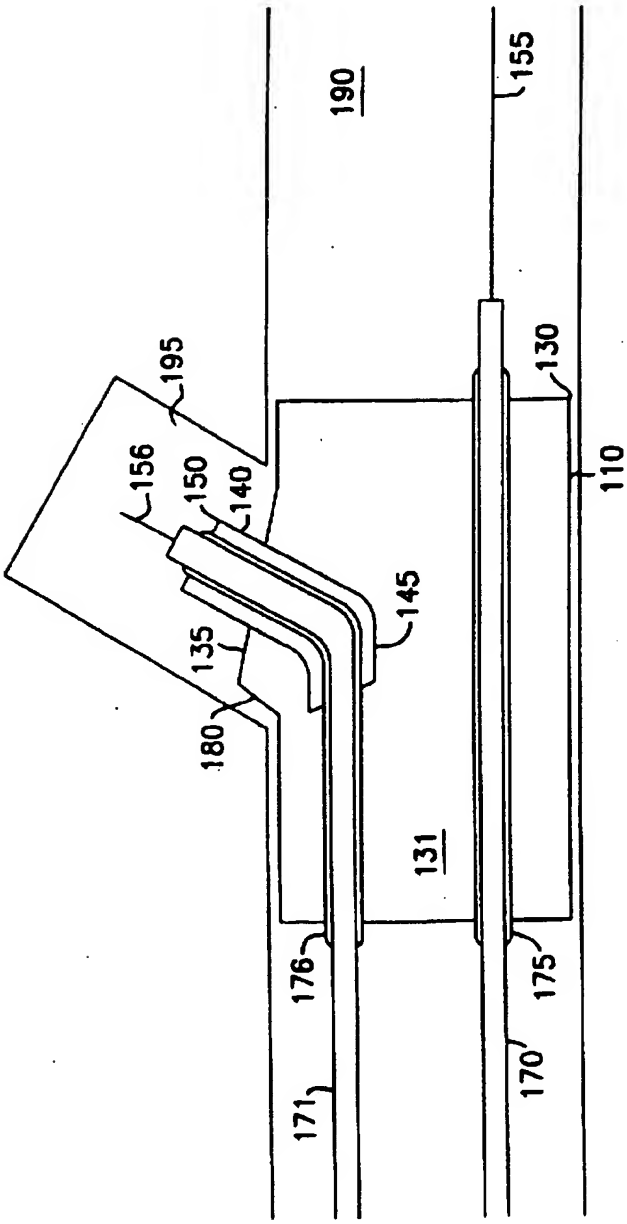



FIG. 19

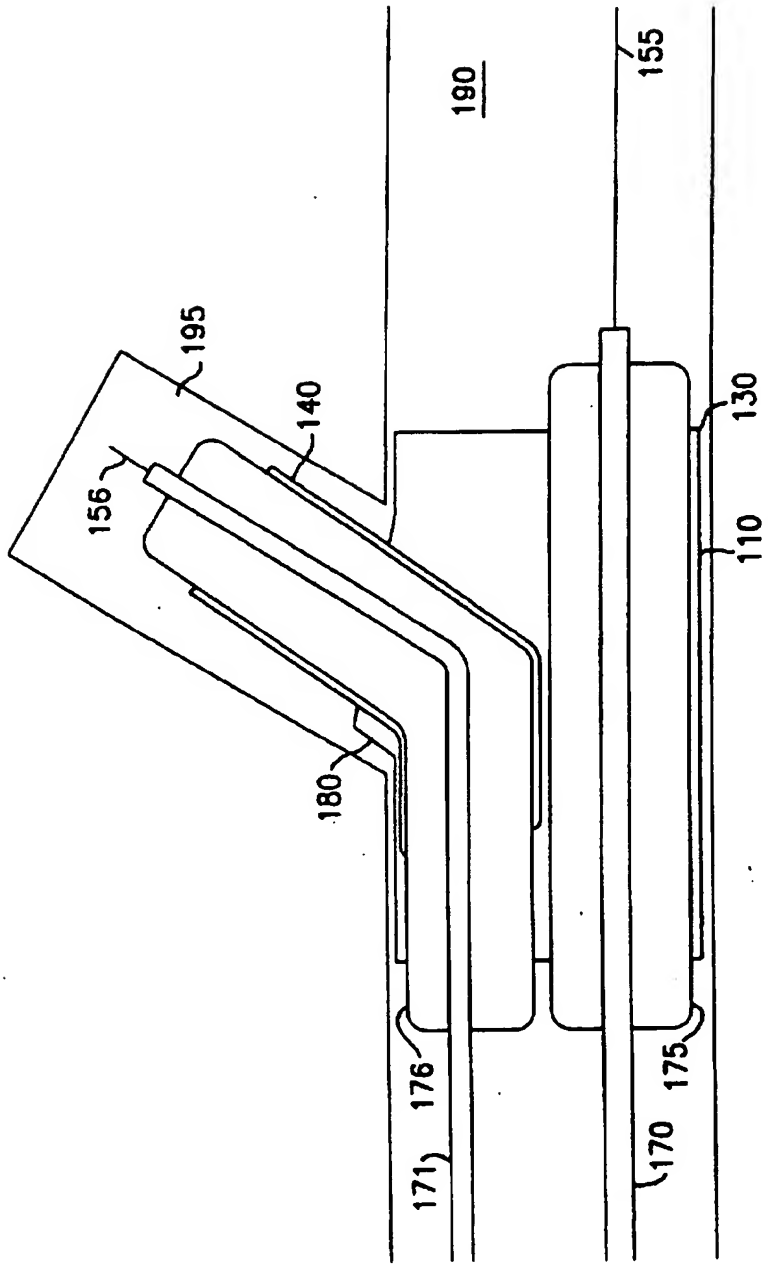



FIG. 20

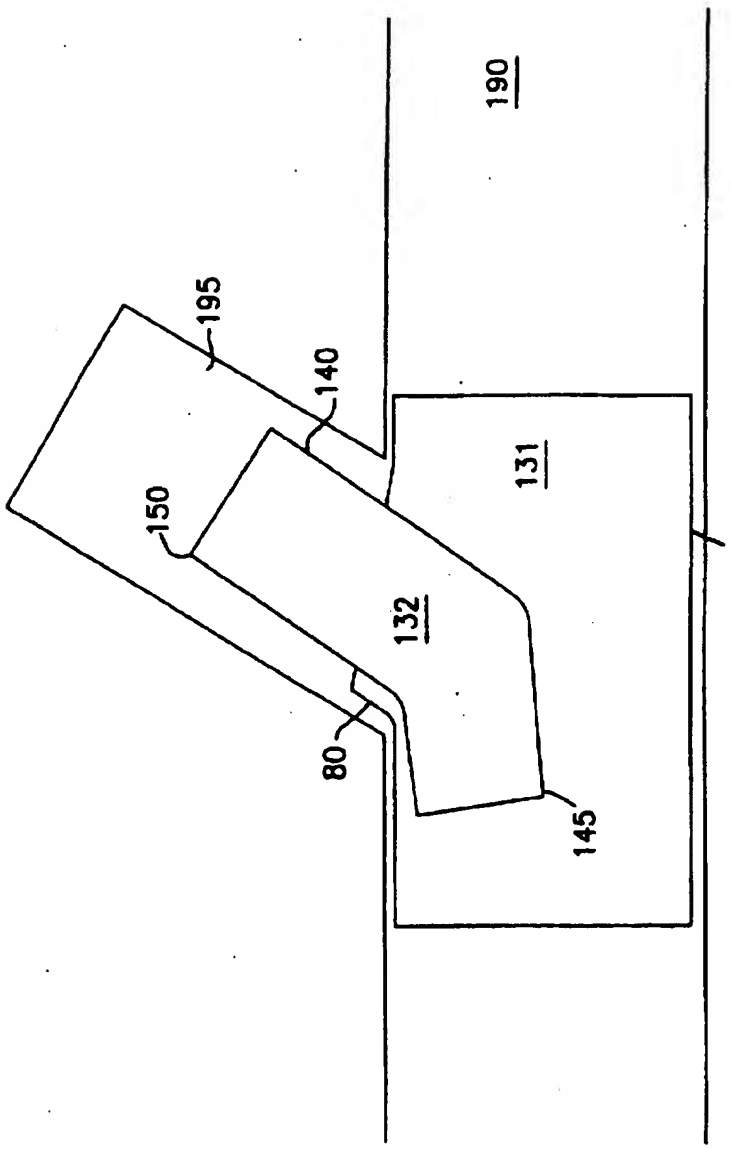



FIG. 21

# BIFURCATED STENT AND METHOD OF MAKING SAME

This application is a division of application Ser. No. 08/642,297, filed on May 3, 1996 now pending.

## FIELD OF THE INVENTION

The present invention relates to stents, and more particularly to bifurcated stents and methods of making bifurcated stents for insertion within a branching vessel.

## BACKGROUND OF THE INVENTION

Stents are well known in the art. They are typically formed of a cylindrical metal mesh which can expand when pressure is internally applied. Alternatively, they can be formed of wire wrapped into a cylindrical shape or sheets of material formed into a cylindrical shape.

Scents are devices which are usually implanted within bodily conduits including the vascular system to reinforce collapsing, partially occluded, weakened, or abnormally dilated sections of the blood vessel. Stents also have been successfully implanted in other areas, e.g., the urinary tract or the bile duct to reinforce such bodily conduits.

U.S. Pat. No. 4,994,071 (MacGregor) discloses an expandable, bifurcating stent having a main cylindrical lattice formed from interconnected, flexible. Two additional cylindrical lattices, having smaller diameters than the main lattice, are similarly constructed. The main lattice includes a flexible wire interconnecting the main lattice to one of the additional lattices. A second flexible wire interconnects the main lattice to the other additional lattice. The flexible wires form backbones that extend axially along the length of the main lattice and along each of the additional lattices. One disadvantage of this bifurcating stent is the complex nature of the interconnection of the flexible wires forming the backbones with the loop structure of each lattice.

## SUMMARY OF THE INVENTION

The present invention solves these and other disadvantages of the prior art by providing bifurcated stents and methods of fabricating and deploying bifurcated stents having a stem portion and two leg portions.

In a first embodiment of the invention, a bifurcated stent is made by providing three sheets patterned to a desired pattern, wherein two sheets are substantially the same size and the third sheet is wider than either of the first two sheets. Each of the sheets is formed into tubes by turning up the longitudinal edges and forming a joint by welding. The larger sheet forms a tube that acts as the stem portion of the bifurcated stent and the other sheets form tubes which act as the leg portions of the bifurcated stent. The two leg portions are then joined to the stem portion to form the bifurcated stent.

In a second embodiment of the invention, the bifurcated stent is formed by preparing two stent sheets. For each sheet, the longitudinal edges of a portion of the sheet are turned up and secured to each other to form one of the two leg portions of the bifurcated stent. The remaining free edges of each of the two sheets are then joined to form the stem portion of the stent.

In a third embodiment, the bifurcated stent comprises first and second tubular portions. The first portion has a proximal end which forms the stem portion and a distal end which forms one of the leg portions of the bifurcated stent. A branch aperture is disposed between the proximal end and the distal end of the first portion. The second portion is introduced into the longitudinal bore of the stem portion of the first portion and is advanced through the branch aperture so that it protrudes beyond the branch aperture to form a second leg. When the second portion is expanded, the proximal end of the second portion engages the material defining the branch aperture so as to secure the second leg in the desired position.



It is an object of this invention to provide a method of making a bifurcated stent, comprising the steps of: a) preparing a first sheet having a first edge, a second edge, a third edge, and a fourth edge; b) preparing a second sheet having a first edge, a second edge, a third edge, and a fourth edge; c) preparing a third sheet having a first edge, a second edge, a third edge, and a fourth edge; d) attaching the second edge to the third edge of the first sheet to form a tubular first leg portion having a proximal end and a distal end; e) attaching the second edge to the third edge of the second sheet to form a tubular second leg portion having a proximal end and a distal end; f) attaching the second edge to the third edge of the third sheet to form a tubular stem portion having a proximal end and a distal end; and g) attaching the proximal end of the first leg portion and the proximal end of the second leg portion to the distal end of the stem portion.

It is another object of this invention to provide a method of making a bifurcated stent, comprising the steps of a) preparing a first sheet having a proximal end and a distal end; b) deforming the distal end of the first sheet to form a first leg and deforming the proximal end of the first sheet to form a first stem half; c) preparing a second sheet having a proximal end and a distal end; d) deforming the distal end of the second sheet to form a second leg and deforming the proximal end of the second sheet to form a second stem half; and e) joining the first stem half to the second stem half to form a stem.

It is yet another object of this invention to provide a method of making a bifurcated stent comprising the steps of a) preparing a first expandable tubular member having a proximal end and a distal end and a longitudinal bore therethrough, the first tubular member provided with a branch aperture disposed between said proximal end and the distal end, the branch aperture communicating with said longitudinal bore and the aperture sized and adapted to receive and secure a second expandable tubular member; b) delivering the first expandable tubular member to a bifurcated vessel having a first lumen and a second lumen so that the first expandable member is disposed within the first lumen and the branch aperture communicates with the second lumen; c) expanding the first expandable member in an amount sufficient to secure the first expandable member in the first lumen; d) preparing a second expandable tubular member having a proximal end and a distal end and having longitudinal bore therethrough; e) widening the branch aperture; f) delivering the second expandable tubular member into the branch aperture so that the distal end of the second expandable tubular member is disposed within the second lumen and the proximal end of the second expandable tubular member is disposed within the longitudinal bore of the first longitudinal member; and g) expanding the second expandable tubular member in an amount sufficient to secure the second expandable tubular member within the second lumen and within said branch aperture.

## BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 shows a bifurcated stent manufactured in accordance with the present invention;

FIG. 2 shows sheets used to form the legs and stem of the stent shown in FIG. 1;

FIG. 3 shows the sheets shown in FIG. 2 after they have been rolled into a tubular shape;

FIG. 4 is a perspective view of the tubes shown in FIG. 3 prior to assembly;

FIG. 5 is an end view of the tubes shown in FIGS. 3 and 4 after they have been assembled to form a stent;

FIG. 6 is a top view of the assembled apparatus shown in FIG. 5;

FIG. 7 shows sheets used to form another embodiment of a bifurcated stent manufactured in accordance with the invention;

FIG. 7B shows sheets used to form another embodiment of a bifurcated stent manufactured in accordance with the invention;

FIG. 8 shows the sheets of FIG. 7 with demarcation points;

FIG. 9 shows the sheets of FIG. 8 after they have been rolled into a tubular shape;

FIG. 9B shows the sheets of FIG. 7B after they have been rolled into a tubular shape;

FIG. 10 shows the tubes of FIG. 9 just prior to assembly;

FIG. 10B shows the tubes of FIG. 9B just prior to assembly;

FIG. 11 is a side view of the tubes shown in FIGS. 9 and 10 after assembly;

FIG. 11B is a side view of the tubes shown in FIGS. 9B and 10B after assembly;

FIG. 12 is an end view of the assembled apparatus shown in FIG. 11;

FIG. 12B is an end view of the assembled apparatus shown in FIG. 11B;

FIG. 12C shows an alternative embodiment of a pattern that may be used in place of the patterns shown in FIGS. 7 and 7B;

FIG. 13 shows a stem and first leg portion and a second leg portion used to form another embodiment of a bifurcated stent manufactured in accordance with this invention;

FIG. 14 shows guide wires disposed in the trunk lumen and branch lumen to be treated;

FIG. 15 shows the stem and first leg portion shown in FIG. 13 disposed on catheters and guide wires prior to introduction into the lumen to be treated;

FIG. 16 shows the stem and first leg portion shown in FIG. 13 after it has been delivered to the bifurcation to be treated and prior to its expansion;

FIG. 17 shows the second leg portion shown in FIG. 16 after it has been expanded;

FIG. 18 shows expansion of the branch aperture;

FIG. 19 shows the unexpanded second leg portion disposed in the branch aperture;

FIG. 20 shows the expansion of the second leg portion shown in FIG. 19; and

FIG. 21 shows the assembled bifurcated stent disposed in the bifurcated lumen to be treated.

## DETAILED DESCRIPTION

In the embodiment illustrated in FIG. 1, the bifurcation stent 5 comprises a first leg 10, a second leg 15, and a stem 20. FIG. 2 shows a first sheet 25 which is used to form first leg 10, a second sheet 30 which is used to form second leg 15, and a third sheet 35 which is used to form stem 20. The first sheet 25 and second sheet 30 are substantially flat and are sized to a predetermined length and width. For many applications, the first sheet 25 and second sheet 30 will have substantially the same dimensions so as to produce legs 10 and 15 that are substantially the same size, however, the legs 10 and 15, and the sheets 25 and 30 used to produce them, may be of varying sizes as specific applications dictate. The stents of this invention may be sized so that when assembled they are their final size, however, in a preferred embodiment the stents are expandable and sized and adapted to assume their final dimensions upon expansion. The stent sheets 70 and 75 may be patterned or etched with perforations forming a variety of patterns as specific applications dictate to achieve the expandable features required as previously discussed. The third sheet 35 is sized so that when it is rolled into a tube its internal cross-section can be made to accommodate the cross-sectional external diameters of first leg 10 and second leg 15. First sheet 25 has a first edge 26, a second edge 27, a third edge 28, and a fourth edge 29. Second sheet 30 has a first edge 31, a second edge 32, a third edge 33, and a fourth edge 34. Third sheet 35 has a first edge 36, a second edge 37, a third edge 38, and a fourth edge 39. After the sheet metal has been cut to form sheets 25, 30, and 35, it is deformed and rolled so as to cause two opposite edges to meet and create a cylinder. In the example shown in FIGS. 2 and 3, edge 27 is joined to edge 29 via weld run 14 to form first leg 10. Edge 32 is joined to edge 34 via weld run 19 to form second leg 15. Edge 37 is joined to edge 39 via weld run 29 to form stem 20. The edges may be joined in a wide variety of ways well known to those skilled in the art as suitable for this purpose, e.g., screwing, crimping, soldering, however, in a preferred embodiment welding is utilized. In an especially preferred embodiment, spot welding is utilized. As shown in FIG. 3, first leg 10 has a proximal end 11, a distal end 12, and defines a longitudinal bore 13. Second leg 15 has a proximal end 16, a distal end 17, and defines a longitudinal bore 18. The stem 20 has a proximal end 26, a distal end 27, and defines a longitudinal bore 28. FIG. 4 shows the first leg 10, second leg 15, and stem 20 just prior to assembly. To form the bifurcated stent 5, the proximal end 11 of first leg 10 and the proximal end 16 of second leg 15 are joined to the distal end 27 of the stem portion 20 so that the longitudinal bores 13, 18, and 28 are in communication with each other. FIG. 5 is an end view and FIG. 6 is a side view of the assembled apparatus.

FIG. 11 shows a second embodiment of a bifurcation stent manufactured in accordance with this invention. The stent 50 is provided with a first leg 55 and a second leg 60 attached to a stem portion 65. The bifurcation stent 50 is formed from a first sheet 70 and a second sheet 75 as shown in FIG. 7. The stent sheets 70 and 75 may be patterned or etched with perforations forming a variety of patterns as specific applications dictate to achieve the expandable features required as previously discussed. The sheets 70 and 75 are substantially flat and have a predetermined length and width. First sheet 70 has a first edge 71, a second edge 72, a third edge 73 and a fourth edge 74. The second sheet 75 has a first edge 76, a second edge 77, a third edge 78, and a fourth edge 79. To form the legs of the stent a portion of edge 72 is rolled towards a portion of edge 74 and a portion of edge 77 is rolled towards a portion of edge 79. Demarcation points 80, 81, 82, and 83 are selected on sheets 70 and 75 as shown in FIG. 8. These demarcation points 80, 81, 82, and 83 are selected to meet the requirement of specific applications and may be adjusted depending upon the length required for legs 55 and 60 and the length required for stem

65. Demarcation points 80 and 81 that are equidistant from edges 73 and 71 and demarcation points 82 and 83 that are equidistant from edges 76 and 78 will result in a stent in which the legs 55 and 60 have a length that is substantially equal to stem portion 65. If the demarcation points are selected to be closer to edges 73 and 78 than to edges 71 and 76 the stem will have a length that is greater than the length of each of the legs. If the demarcation points are selected to be closer to edges 71 and 76 than to edges 73 and 78, each of the legs 60 and 65 will have a length that is greater than the length of the stem 65. In a preferred embodiment, however, the demarcation points 80, 81, 82, and 83, are selected so that proximal edges 72", 74", 77", and 79" are about ⅓ the length of edges 72, 74, 77, and 79. As shown in FIG. 8, demarcation point 80 divides edge 72 at approximately its midpoint into a distal edge 72' and a proximal edge 72". Demarcation point 81 divides edge 74 at approximately its midpoint into a distal edge 74' and a proximal edge 74". Demarcation point 82 divides edge 77 at approximately its midpoint into a distal edge 77' and a proximal edge 77" and demarcation point 83 divides edge 79 at approximately its midpoint into a distal edge 79' and a proximal edge 79".

To form the stent, edge 72' is connected to edge 74' via weld run 90 to form first member 95 having a first leg portion 55 and a first stem half 65' as shown in FIG. 9. Edge 77' is connected to edge 79' via weld run 91 to form second member 100 having a second leg portion 60 and a second stem half 65". As previously discussed, the edges may be connected in a variety of ways well known to those skilled in the art. FIG. 10 shows the first member 95 and the second member 100 shown in FIG. 9 in alignment just prior to assembly. To produce the bifurcated stent 50 shown in FIGS. 11 and 12, edge 72" is connected to edge 79" via weld run 92 and edge 74" is connected to edge 77" via weld run 93 so that first stem half 65' and second stem half 65" form stem 65. FIG. 12 is a cross-sectional end view of the stent shown in FIG. 11.

In the embodiment shown in FIG. 7, sheets 70 and 75 are squares or rectangles. The sheets 70 and 75 are not limited to this configuration, however, as shown in FIG. 7B. FIG. 11B shows a bifurcation stent manufactured using the sheets 270 and 275 shown in FIG. 7B. The stent 250 is provided with a first leg 255 and a second leg 260 attached to a stem portion 265. The bifurcation stent 250 is formed from a first sheet 270 and a second sheet 275 as shown in FIG. 7B. The stent sheets 270 and 275 may be sized and etched as previously discussed. As shown in FIG. 7B, first sheet 270 has a first edge 271, a second edge 272, a third edge 273, a fourth edge 274, a fifth edge 275, and a sixth edge 276, a seventh edge 146, and an eighth edge 147. The second sheet 275 has a first edge 277, a second edge 278, a third edge 279, a fourth edge 280, a fifth edge 281, a sixth edge 282, a seventh edge 148, and an eighth edge 149. As shown in FIG. 9B, edge 274 is connected to edge 276 via weld run 290 to form first member 295 having a first leg portion 255 and a first stem half 265'. Edge 280 is connected to edge 282 via weld run 291 to form second member 300 having a second leg portion 260 and a second stem half 265". As previously discussed, the edges may be connected in a variety of ways well known to those skilled in the art. FIG. 10B shows the first member 295 and the second member 300 shown in FIG. 9B in alignment just prior to assembly. To produce the bifurcated stent 250 shown in FIGS. 11B and 12B, edge 272 is connected to edge 149 via weld run 292 and edge 278 is connected to edge 147 via weld run 293 so that first stem half 265' and second stem half 265" form stem 265. FIG. 12B is a cross-sectional end view of the stent shown in FIG. 11B. FIG. 12C shows an alternative pattern that may be used in place of the patterns shown in FIGS. 7 and 7B.

A third embodiment of this invention comprises two portions which are deployed serially in two steps and assembled within the patient to form a bifurcated stent. FIG. 13 shows stem and first leg portion 110 provided with a longitudinal bore 131 and having a proximal end 115 defining a stem portion 125 and a distal end 120 defining a first leg portion 130. Second leg portion 140 is provided with a longitudinal bore 132 and has a proximal end 145 and a distal end 150. Stem and firs leg portion 110 and second leg portion 140 may be sized and patterned or etched as previously discussed. A branch aperture 135 is disposed between the proximal end 115 and the distal end 120 of stem and first leg portion 110. The branch aperture 135 is sized to receive second leg portion 140 and is adapted to engage and secure the second leg portion 140 when it has been expanded within the branch aperture 135. Second leg portion 140 is sized and adapted to engage and be secured into branch aperture 135 upon expansion. FIGS. 14 to 21 show how the bifurcated stent is assembled within a bifurcated lumen. As shown in FIGS. 14 to 21, the area to be treated is a bifurcated lumen having a first or trunk lumen 190 and a second or branch lumen 195. As shown in FIG. 14, a first guide wire 155 is introduced into the trunk lumen 190 and a second guide wire 156 is introduced into the branch lumen 195. As shown in FIG. 15, a balloon expandable stem and first leg portion 110 is disposed on the tip of a first balloon catheter 170 so that the balloon 175 is disposed within longitudinal bore 131. A second balloon catheter 171 is then introduced into longitudinal bore 131 of stem and first leg portion 110 and is advanced so that the balloon 176 is disposed within aperture 135. First catheter 170 is mounted on first guide wire 155 and second catheter 171 is mounted on second guide wire 156. As shown in FIG. 16, the unexpanded stem and first leg portion 110 is guided to the area to be treated so that first leg portion 130 is disposed within trunk lumen 190 and branch aperture 135 communicates with branch lumen 195. Guide wire 156 facilitates the orientation of the branch aperture 135 with the branch lumen 195. The size of the conventional catheters and balloons is not to scale and details well known to those skilled in the art have been omitted for clarity. Balloon 175 is inflated which causes the stem and first leg portion 110 to expand, as shown in FIG. 17, to secure it in the desired position. After expansion, the external wall of stem and first leg portion 110 would contact the interior walls of trunk lumen 190, however, a gap has been intentionally left for clarity. The balloon 175 on first catheter 170 is left inflated and the balloon 176 on second catheter 171 is then inflated to enlarge the branch aperture 135 as shown in FIG. 18. As the branch aperture 135 is enlarged a portion of the stent defining the branch aperture 135 is pushed outward to form a branch securing lip 180.

Balloons 175 and 176 are deflated, second catheter 171 is withdrawn, and second guide wire 156 is left in place in the branch lumen 195. Second leg portion 140 is then applied to second catheter 171 so that first balloon 176 is disposed in longitudinal bore 132 and second catheter 171 is then applied to second guide wire 156. Second leg portion 140 is then guided to, and introduced into, the longitudinal bore 131 of the stem and first leg portion 110 and is advanced and passed through branch aperture 135 so that the distal end 150 of the second leg portion 140 protrudes into the branch lumen 195 and the proximal end 145 communicates with longitudinal bore 131, as shown in FIG. 19. The balloon 176 on second catheter 171 is partially inflated and the balloon

175 on first catheter 170 is then partially inflated to a pressure substantially equal to the pressure in balloon 176. Both balloons 175 and 176 are then simultaneously inflated to substantially equal pressures. As shown in FIG. 20, inflation of the balloon 176 on second catheter 171 causes second leg member 140 to expand so that its external walls engage and are secured to the area surrounding aperture 135. Inflation of the balloon 175 on the first catheter 170 prevents stem and first leg portion 110 from collapsing when balloon 176 is inflated. After expansion, the external walls of second leg 140 would contact the inner wall of lumen 195, however, a gap has been intentionally left for clarity. The balloons 175 and 176 are deflated, catheters 170 and 171 and guide wires 155 and 156 are withdrawn, and the assembled bifurcated stent 160 is left in place as shown in FIG. 21.

What is claimed is:

1. A method of making a bifurcated stent comprising the steps of:

a) preparing a first expandable tubular member having a proximal end and a distal end and a longitudinal bore therethrough, said first tubular member provided with a branch aperture disposed between said proximal end and said distal end, said branch aperture communicating with said longitudinal bore and said aperture sized and adapted to receive and secure a second expandable tubular member;

b) delivering said first expandable tubular member to a bifurcated vessel having a first lumen and a second lumen so that said first expandable member is disposed within said first lumen and said branch aperture communicates with said second lumen;

c) expanding said first expandable member in an amount sufficient to secure said first expandable member in said first lumen;

d) preparing said second expandable tubular member having a proximal end and a distal end having longitudinal bore therethrough;

e) widening said branch aperture in an amount sufficient to form a branch securing lip;

f) delivering said second expandable tubular member into said branch aperture so that said distal end of said second expandable tubular member is disposed within said second lumen and said proximal end of said second expandable tubular member is disposed within said longitudinal bore of said first longitudinal member; and

g) expanding said second expandable tubular member is an amount sufficient to secure said second expandable tubular member within said second lumen and within said branch aperture.

2. The method of claim 1, wherein said delivering steps b and f and said expanding steps c and g and said widening step e are carried out using a balloon catheter.

3. The method of claim 2, wherein said branch securing lip is formed during step e.

4. A method of making a bifurcated stent comprising the steps of:

a) preparing a first expandable tubular member having a proximal end and a distal end and a longitudinal bore therethrough, said first tubular member provided with a branch aperture disposed between said proximal end and said distal end, said branch aperture communicating with said longitudinal bore and said aperture sized and adapted to receive and secure a second expandable tubular member;

b) delivering said first expandable tubular member to a bifurcated vessel having a first lumen and a second lumen so that said first expandable member is disposed within said first lumen and said branch aperture communicates with said second lumen;

c) expanding said first expandable member in an amount sufficient to secure said first expandable member in said first lumen;

d) preparing said second expandable tubular member having a proximal end and a distal end and having a longitudinal bore therethrough;

e) delivering said second expandable tubular member into said branch aperture so that said distal end of said second expandable tubular member is disposed within said second lumen and said proximal end of said second expandable tubular member is disposed within said longitudinal bore of said first longitudinal member, and

f) expanding said second expandable tubular member in an amount sufficient to form a branch securing lip and in an amount sufficient to secure said second expandable tubular member within said second lumen and within said branch aperture.

* * * * *

US005676696A

# United States Patent [19]

Marcade

[11] Patent Number: 5,676,696

[45] Date of Patent: Oct. 14, 1997

[54] **MODULAR BIFURCATED INTRALUMINAL GRAFTS AND METHODS FOR DELIVERING AND ASSEMBLING SAME**

[75] Inventor: **Jean Paul Marcade**, La Rochelle, France

[73] Assignee: **InterVascular, Inc.**, Clearwater, Fla.

[21] Appl. No.: **642,343**

[22] Filed: **May 3, 1996**

**Related U.S. Application Data**

[62] Division of Ser. No. 393,701, Feb. 24, 1995.

[51] **Int. Cl.**[6] ..... **A61F 2/06**; A61M 29/00

[52] **U.S. Cl.** ..... **623/1**; 606/191

[58] **Field of Search** ..... 623/1, 12; 606/198, 606/191, 153, 108, 194, 195

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*Primary Examiner*—David H. Willse

*Attorney, Agent, or Firm*—Lerner, David, Littenberg, Krumholz & Mentlik

[57] **ABSTRACT**

A bifurcated graft is formed from a series of individual components which are intraluminally delivered apart from one another and then assembled to form a fully supported structure. The modular system includes a base member and one or more grafts connected thereto. The base member preferably includes a portion which gradually increases in diameter. A tubular device for inserting the components of the modular system and a method employing the modular system for repairing an abdominal aortic aneurysm are also disclosed.

**8 Claims, 11 Drawing Sheets**

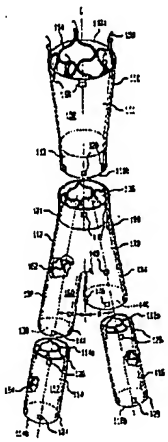

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FIG. 1

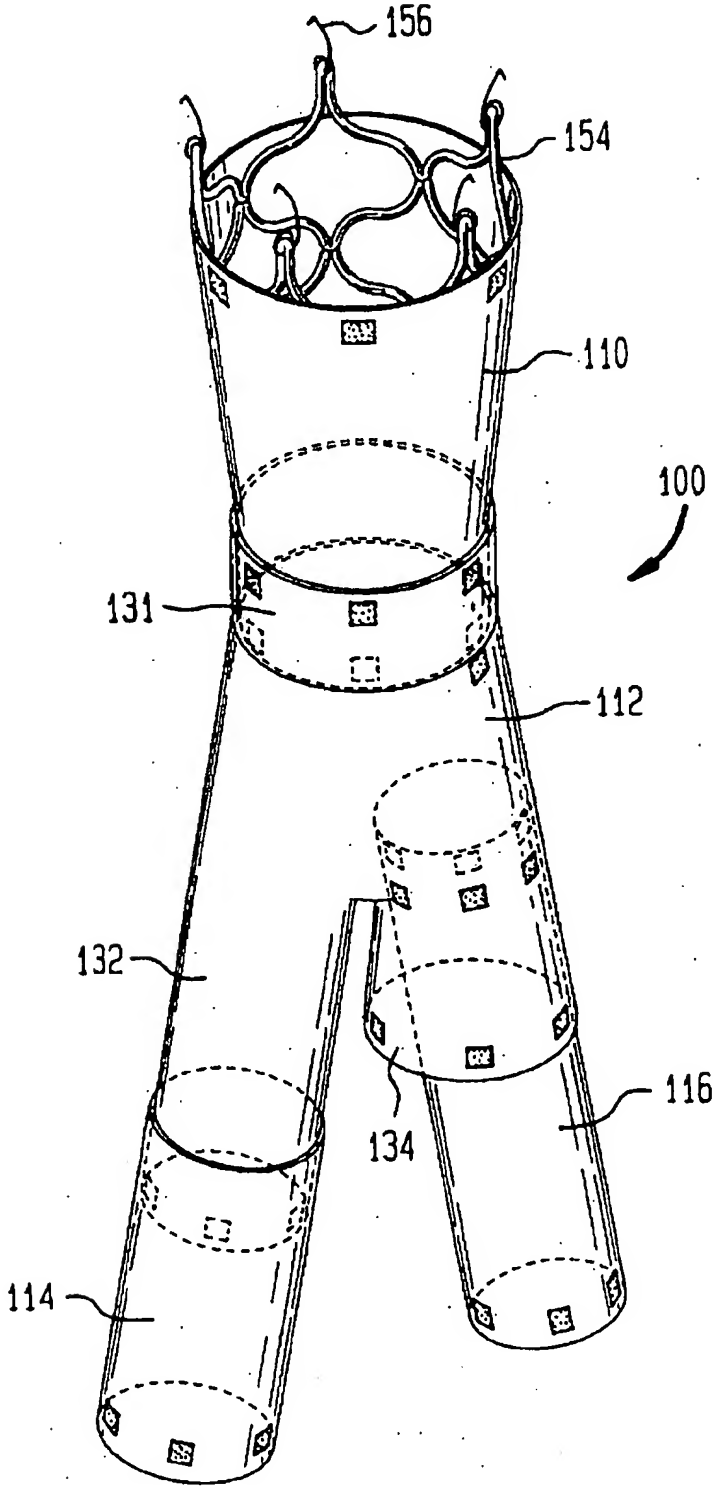
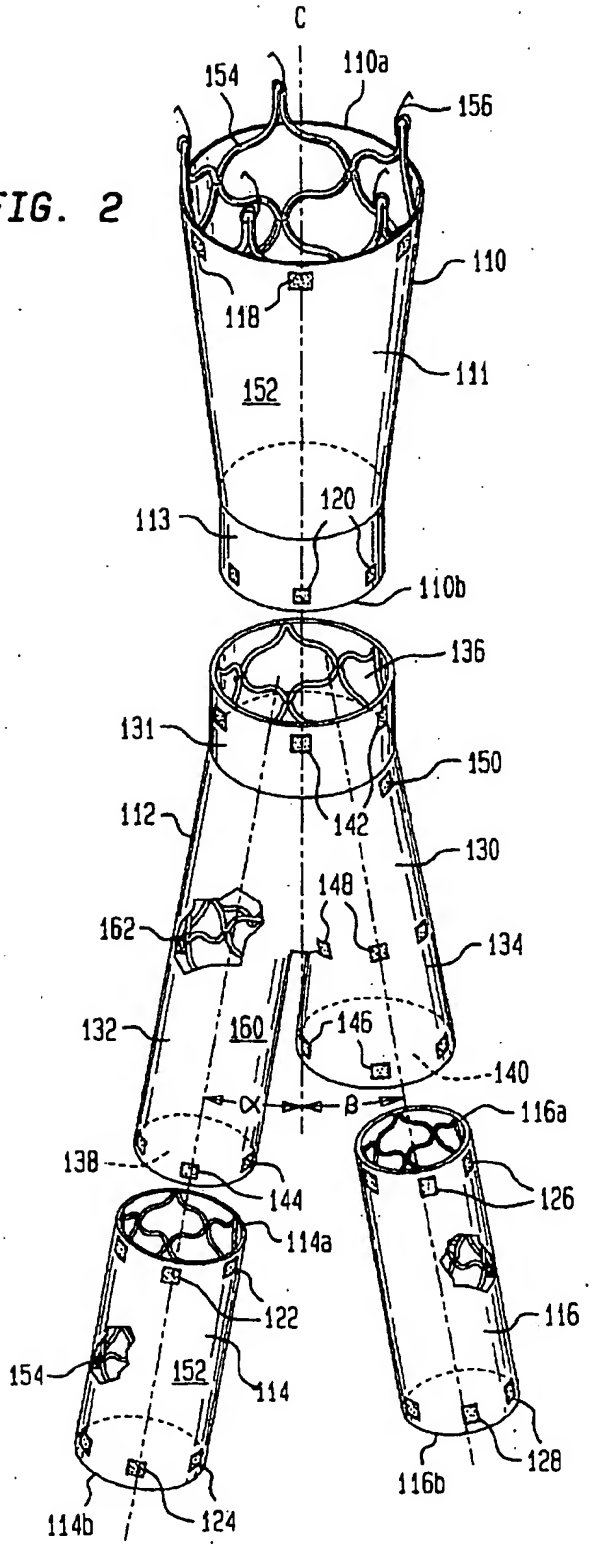


FIG. 2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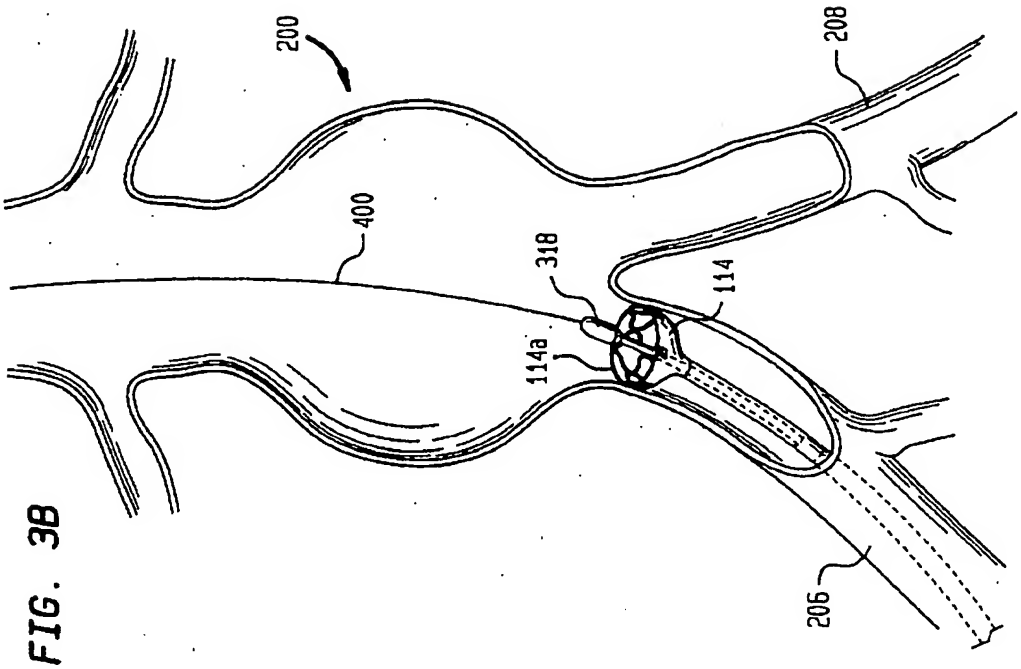


FIG. 3B

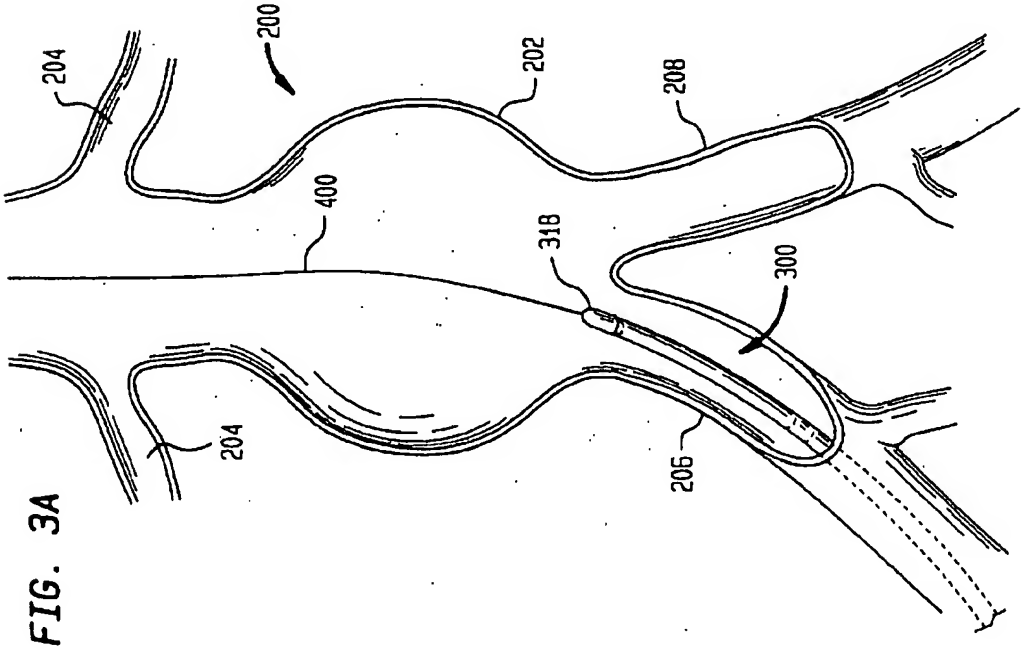


FIG. 3A

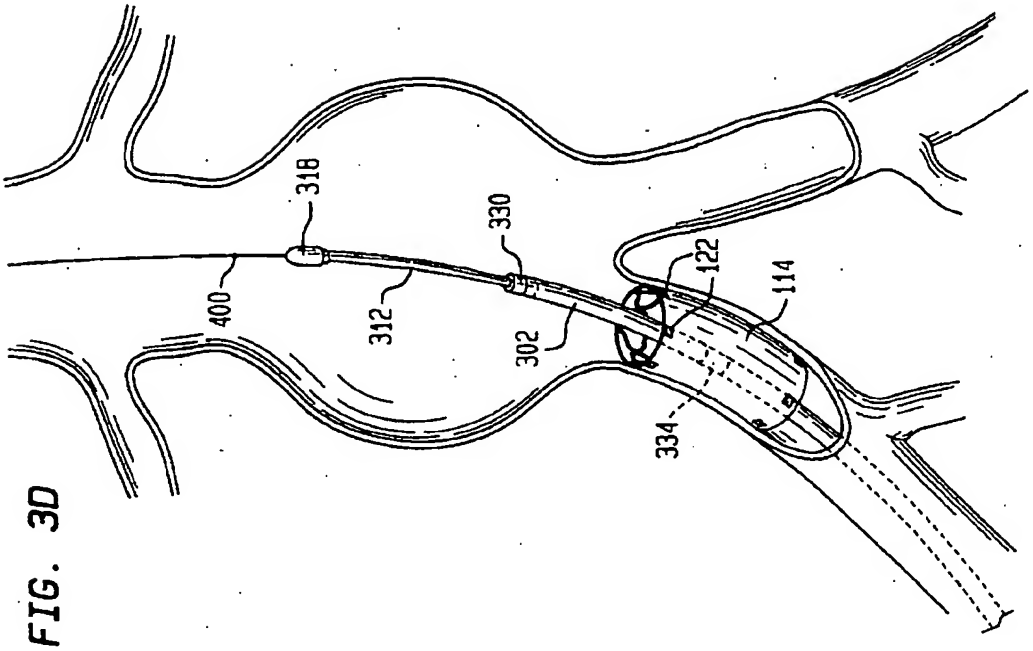


FIG. 3D

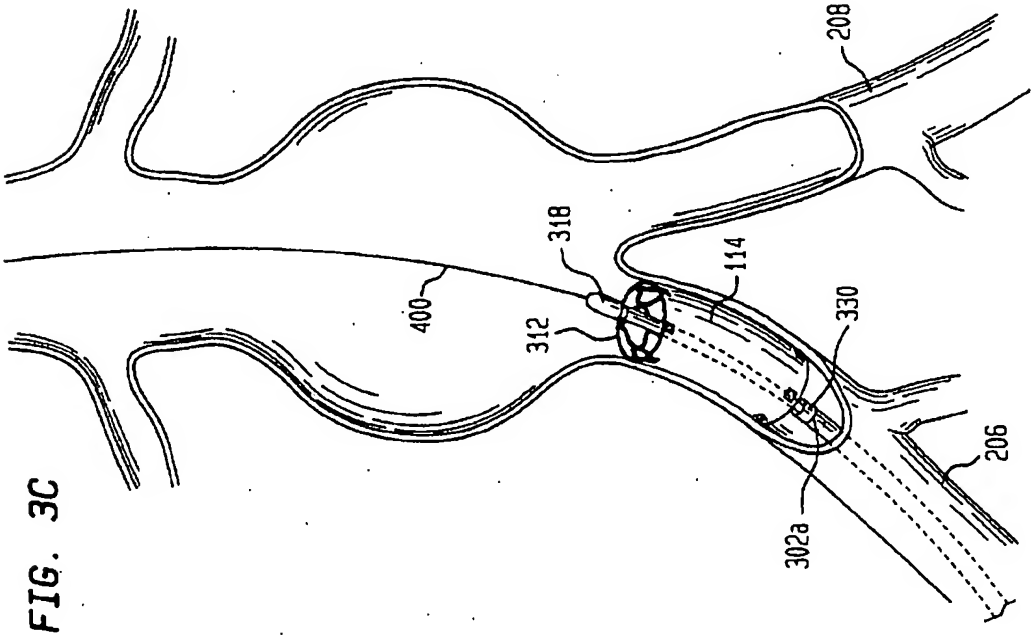


FIG. 3C

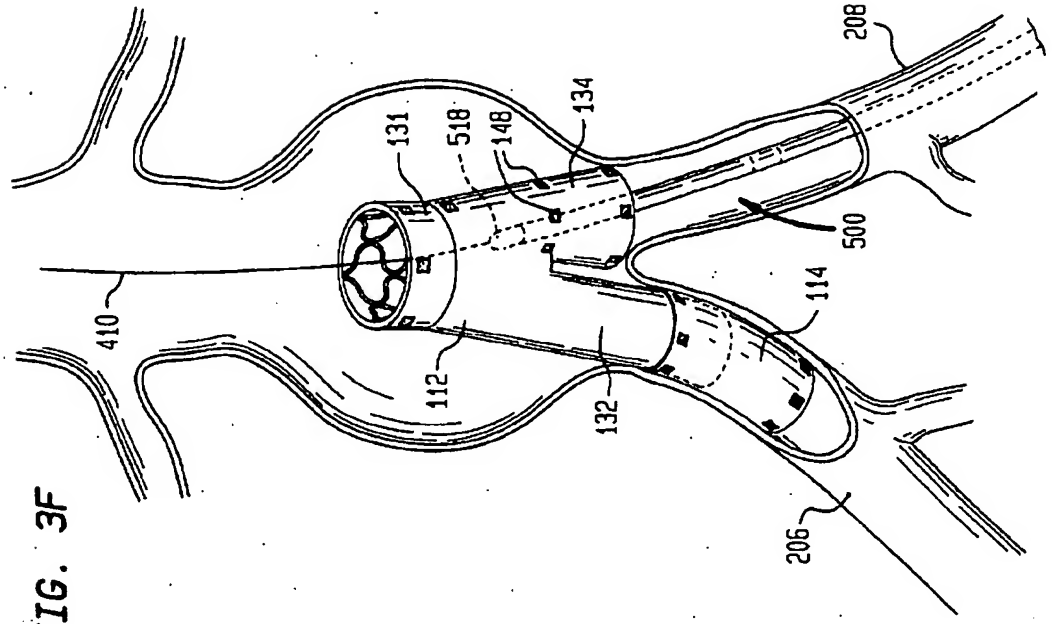
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FIG. 3F

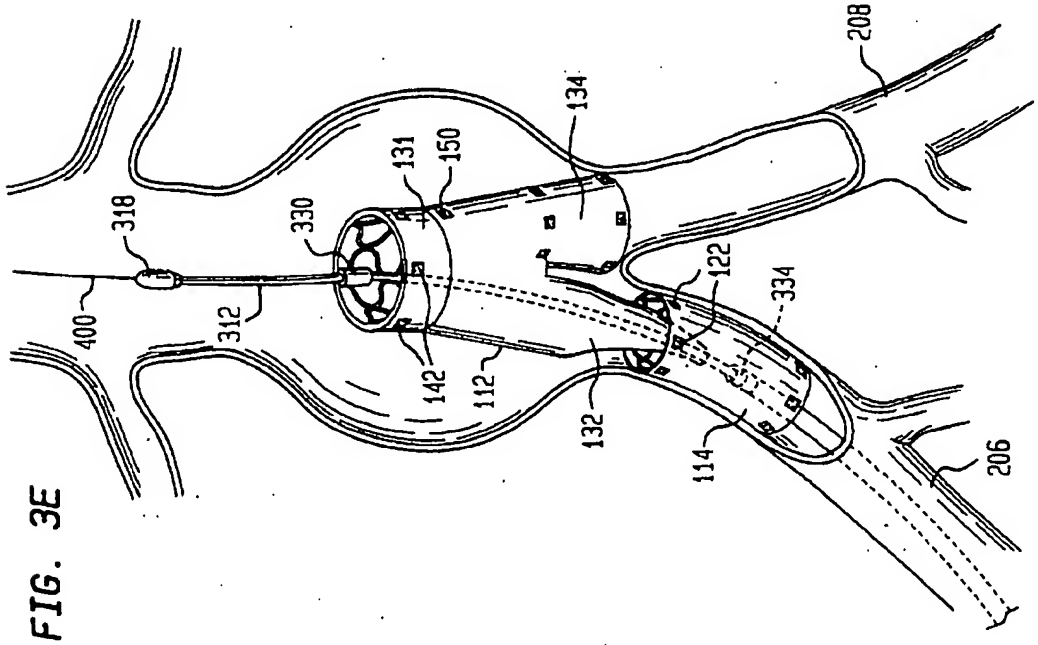
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FIG. 3E

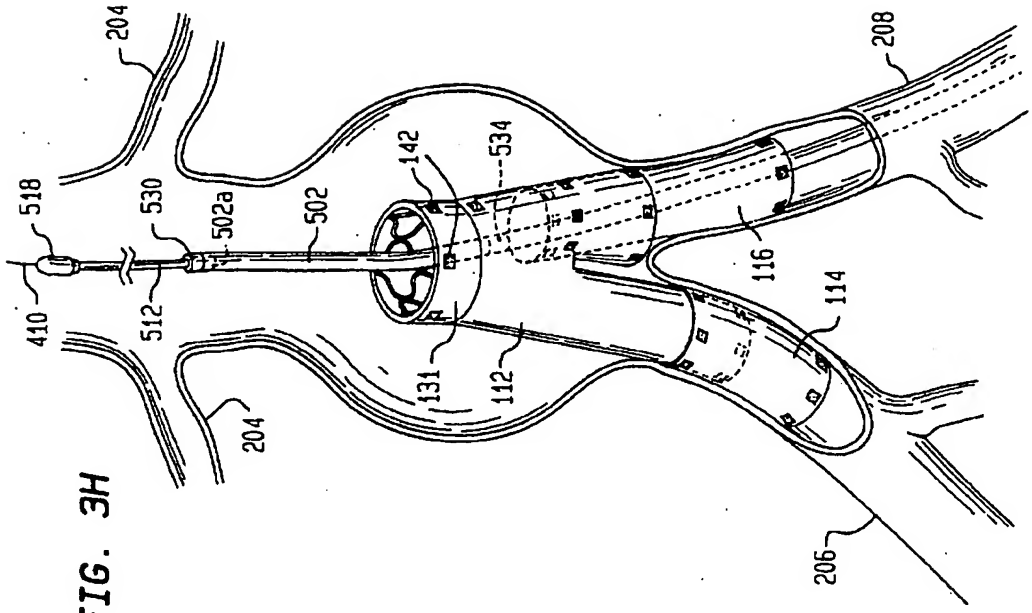
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FIG. 3H

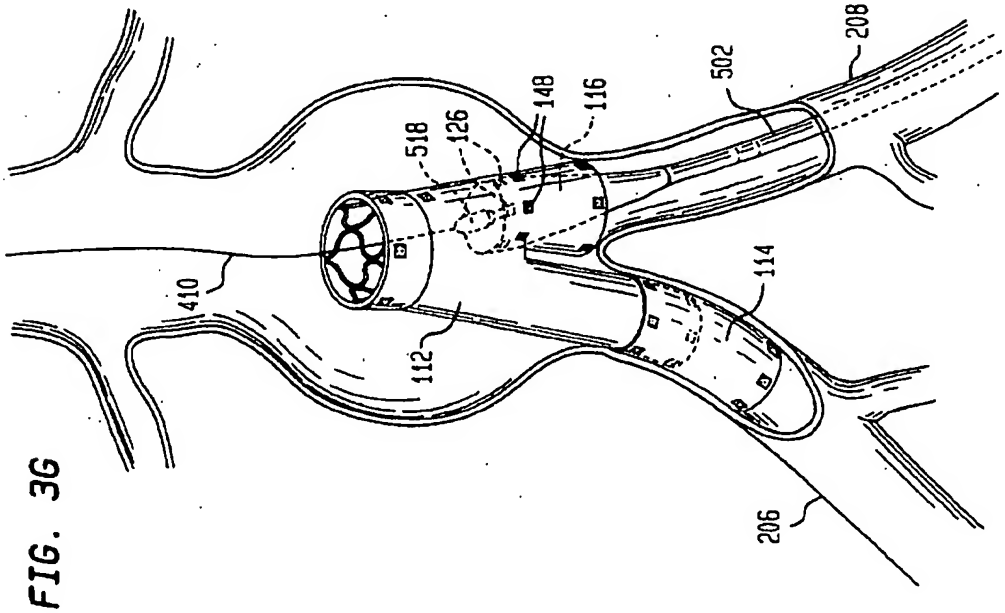
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FIG. 3G

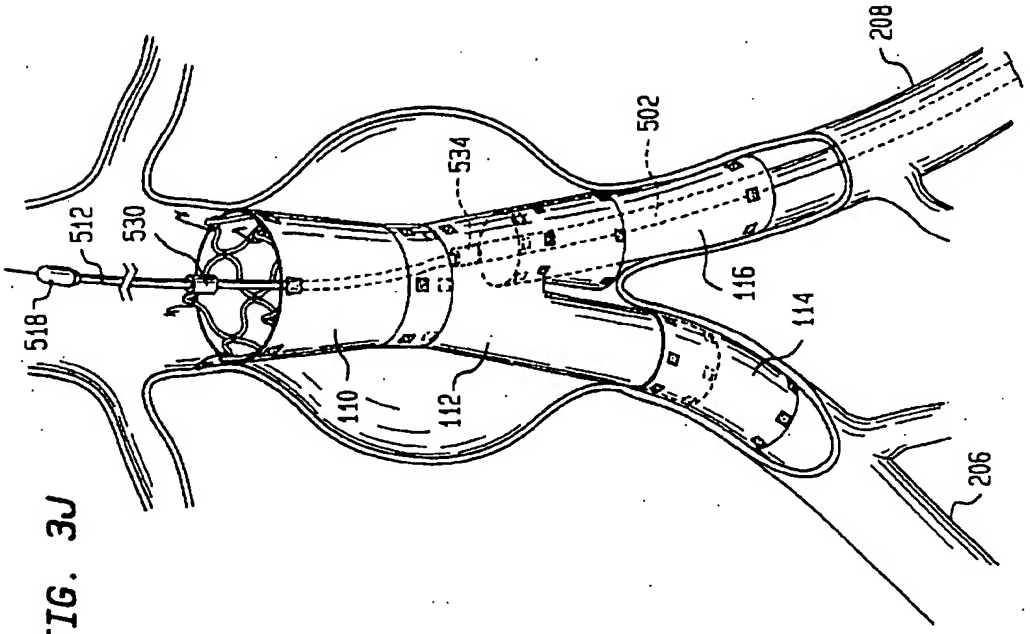
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FIG. 3J

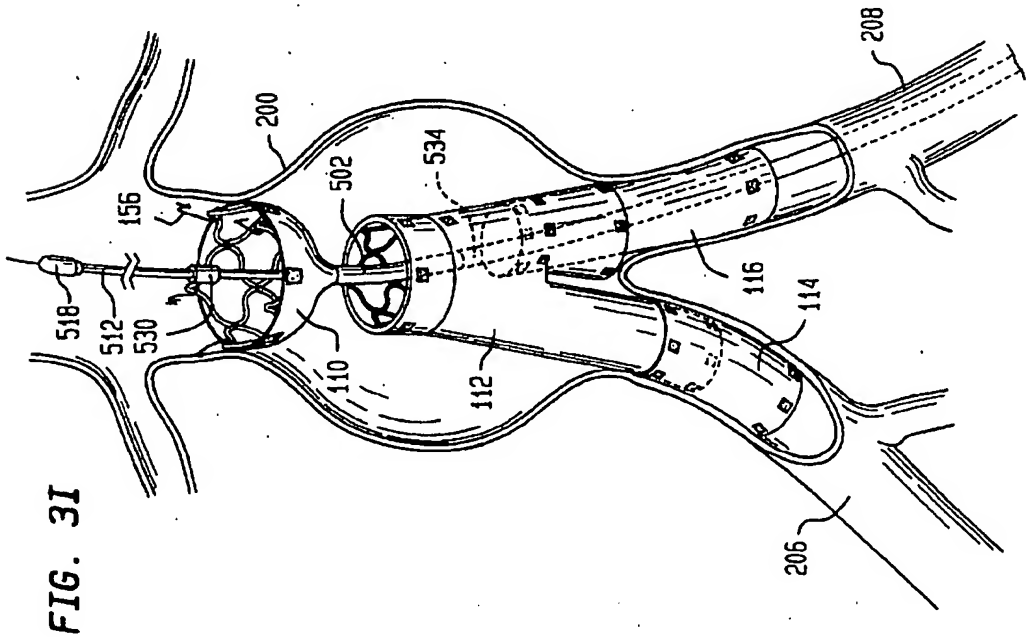
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FIG. 3I

FIG. 4

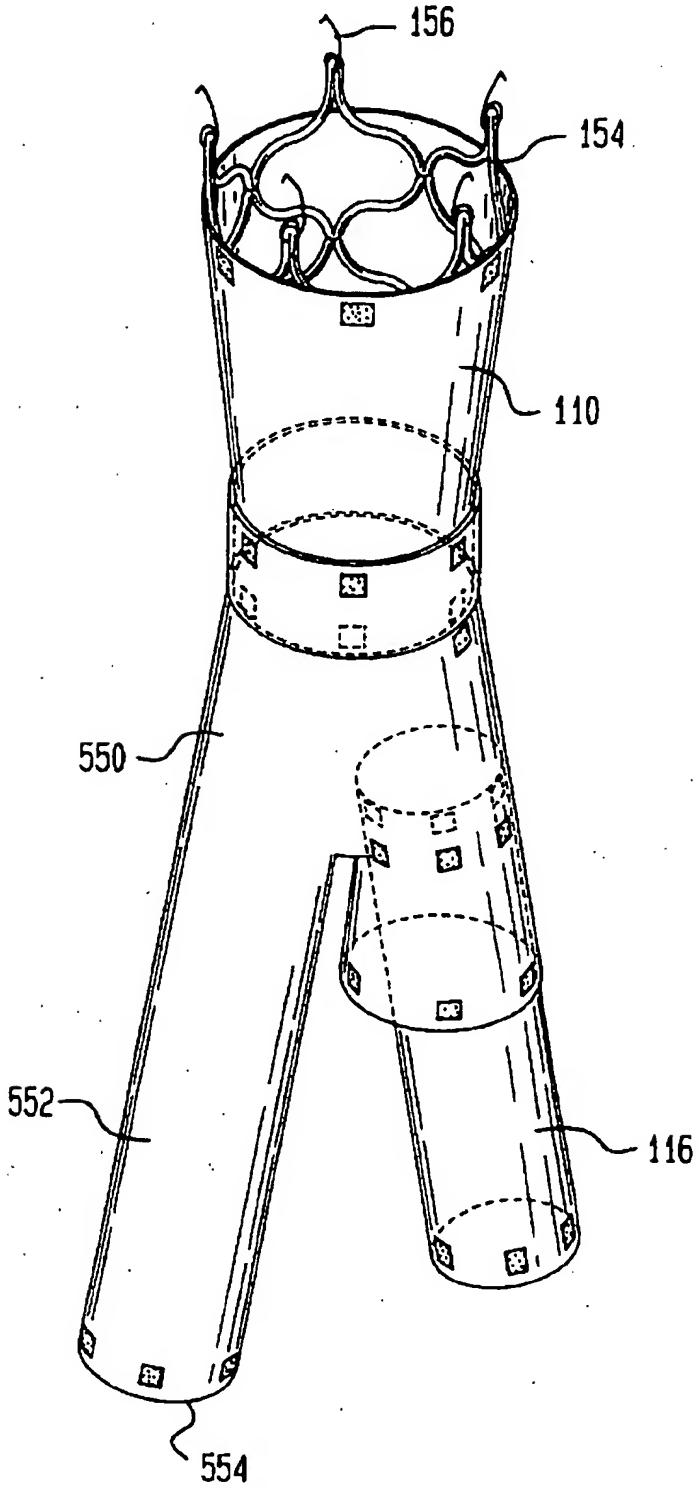


FIG. 5

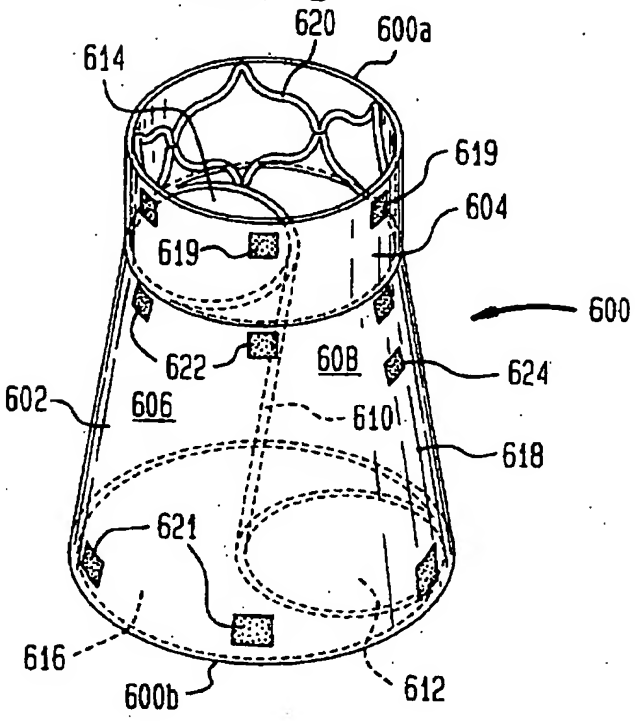

620
600a
614
619
604
619
600
622
608
624
602
606
610
618
621
616
600b
612

FIG. 6

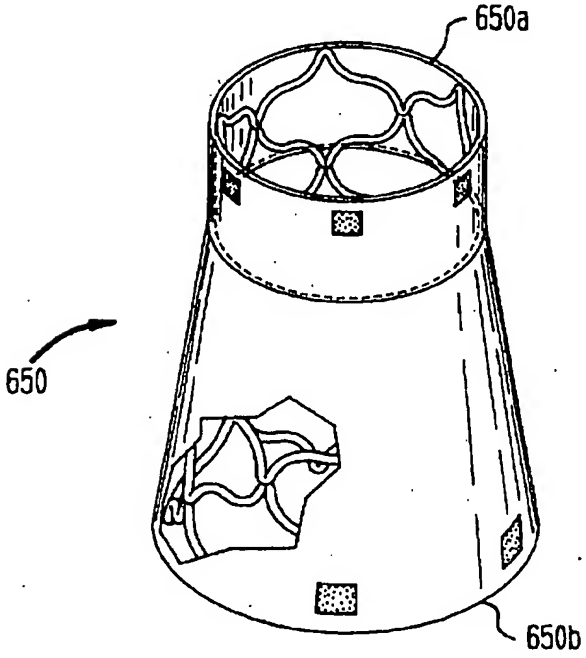

650a
650
650b

FIG. 7

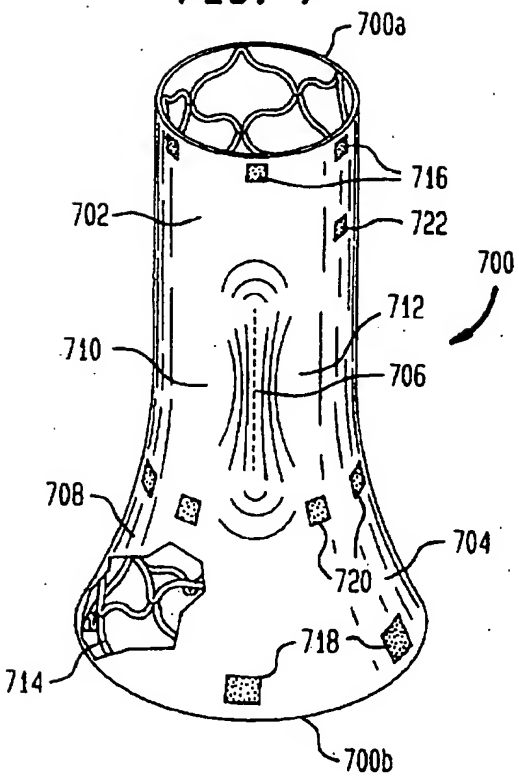
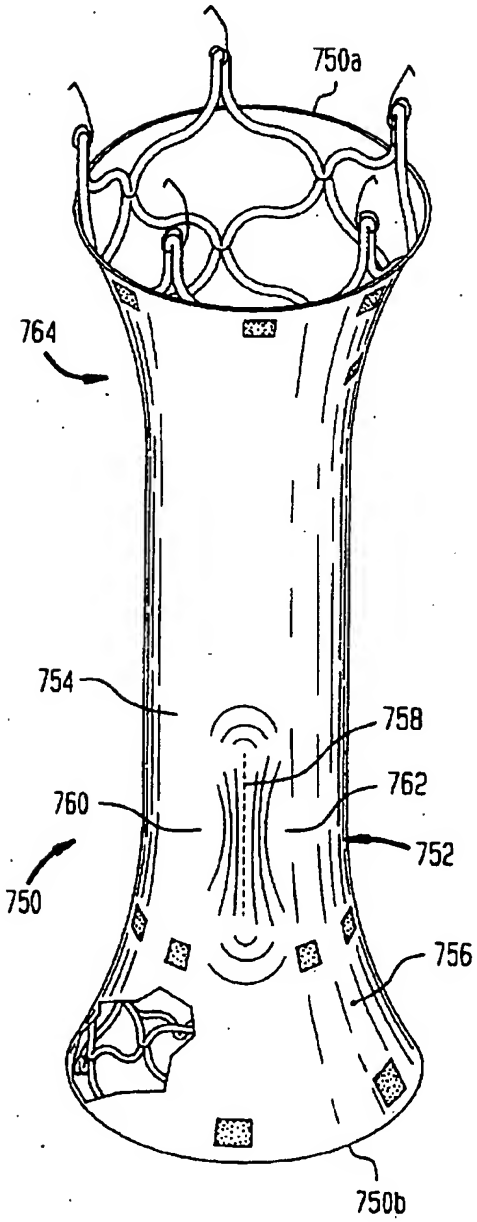

700a
716
702
722
700
712
710
706
708
704
720
718
714
700b

FIG. 8


750a
764
754
758
760
762
752
750
756
750b

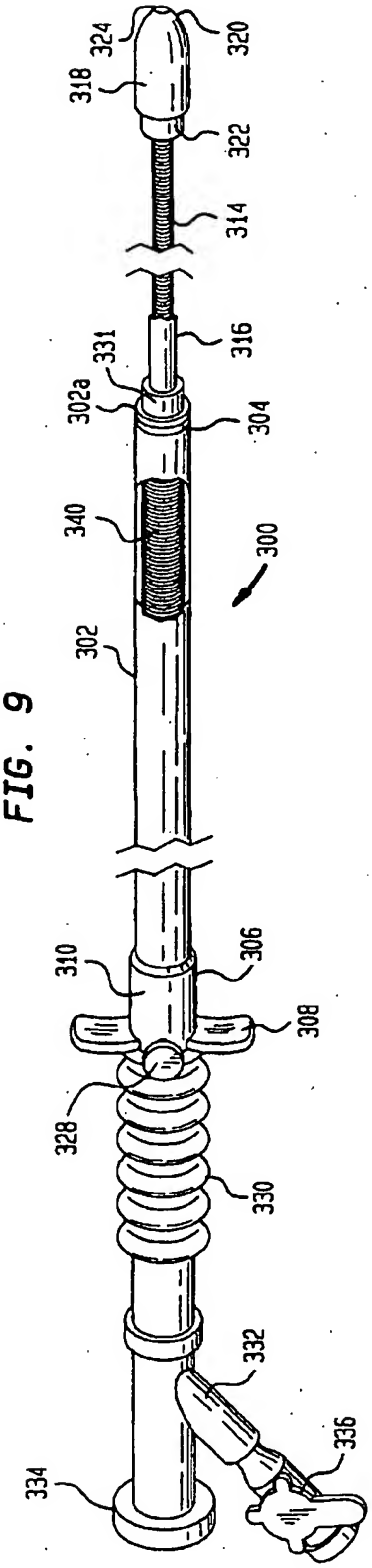

324
320
318
322
314
316
331
302a
304
340
300
302
310
306
308
328
330
332
336
334

FIG. 9

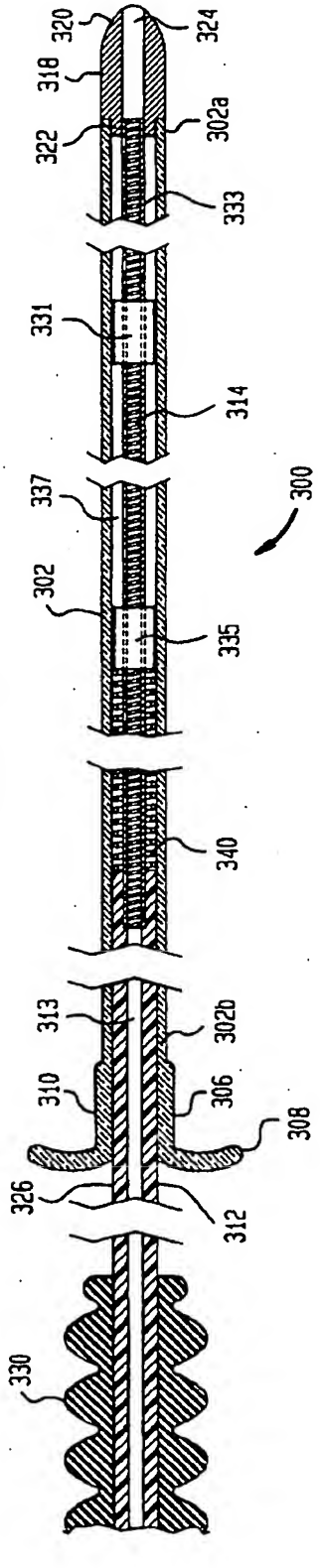

320
324
318
302a
322
333
331
314
337
300
302
335
340
313
302b
310
306
308
326
312
330

FIG. 10

# MODULAR BIFURCATED INTRALUMINAL GRAFTS AND METHODS FOR DELIVERING AND ASSEMBLING SAME

This is a division of application Ser. No. 08/393,701 filed Feb. 24, 1995.

## FIELD OF THE INVENTION

The present invention relates to bifurcated intraluminal grafts, particularly for repairing defects in arteries and other lumens within the body. More particularly, the present invention relates to modular systems for forming bifurcated grafts and to methods for delivering and assembling same in situ for repairing defective body lumens, and particularly abdominal aortic aneurysms.

## BACKGROUND OF THE INVENTION

An abdominal aortic aneurysm is a sac caused by an abnormal dilation of the wall of the aorta as it passes through the abdomen. The aorta is the main artery of the body, supplying blood to all organs and parts of the body except the lungs. It arises from the left ventricle of the heart, passes upward, bends over and passes down through the thorax and through the abdomen, and finally divides into the two iliac arteries which supply blood to the pelvis and lower extremities.

The aneurysm ordinarily occurs in the portion of the aorta below the kidneys. When left untreated, the aneurysm will eventually cause the sac to rupture with ensuing fatal hemorrhaging in a very short time. The repair of abdominal aortic aneurysms has typically required major abdominal surgery in which the diseased and aneurysmal segment of the aorta is removed and replaced with a prosthetic device, such as a synthetic graft.

As with all major surgeries, there are many disadvantages to the foregoing surgical technique, the foremost of which is the high mortality and morbidity rate associated with surgical intervention of this magnitude. Other disadvantages of conventional surgical repair include the extensive recovery period associated with such surgery; difficulties in suturing the graft to the aorta; the loss of the existing thrombosis to support and reinforce the graft; the unsuitability of the surgery for many patients, particularly older patients exhibiting co-morbid conditions; and the problems associated with performing the surgical procedure on an emergency basis after the aneurysm has already ruptured.

In view of the foregoing disadvantages of conventional surgical repair techniques, techniques have been developed for repairing abdominal aortic aneurysms by intraluminally delivering an aortic graft to the aneurysm site through the use of a catheter based delivery system, and securing the graft within the aorta using an expandable stent. Since the first documented clinical application of this technique was reported by Parodi et al. in the Annals of Vascular Surgery, volume 5, pages 491–499 (1991), the technique has gained more widespread recognition and is being used more commonly. As vascular surgeons have become more experienced with this endovascular technique, however, certain problems have been encountered. One problem has been the difficult nature of the procedure. Particularly complex is the step of transferring one leg of the graft from one iliac artery to the other, which requires the careful manipulation of numerous catheters and guide wires. Another problem has been the kinking and/or twisting of the graft both during and after the graft has been implanted. Still other problems relate to the need for accurate preoperative measurements to be made on the morphology of the aneurysm and the surrounding arterial structure, including the length of the aneurysm, the infrarenal aortic length and diameter, the length and diameter of the aorta between the aneurysm and the iliacs, the diameter of the iliacs, and the angle between the iliacs and the aorta. The difficulty in making these measurements accurately and the wide variations in these measurements among patients mandates that the bifurcated grafts be available in a wide range of sizes and configurations.



There therefore exists a need for a bifurcated graft and an implantation method which will overcome the foregoing deficiencies of the prior art. More particularly, there exists a need for a modular graft system which will more accurately accommodate the widely varying arterial sizes in patients, as well as the other size considerations faced by the surgeon. There also exists a need for a method for delivering and implanting a bifurcated graft which avoids the complex procedure for implanting prior art bifurcated grafts.

## SUMMARY OF THE INVENTION

The present invention addresses the needs.

One aspect of the present invention provides a modular prosthesis for repairing a tubular anatomical structure consisting of a base member foldable radially between a collapsed configuration and an expanded configuration and extending longitudinally between a proximal end and a distal end, a primary tubular limb foldable radially between a collapsed configuration and an expanded configuration and having a proximal end and a distal end, and joining means for intraluminally joining the distal end of the primary limb to the proximal end of the base member. Preferably, the joining means includes a friction fit engagement between the distal end of the primary limb in the expanded configuration and the proximal end of the base member in the expanded configuration.

In accordance with one embodiment of the modular prosthesis, the primary limb may have a first diameter at its proximal end and a second diameter less that the first diameter at its distal end. In this regard, the diameter of the primary limb may decrease from the proximal end toward the distal end at an angle of taper between about 2 degrees and about 15 degrees. In preferred embodiments, the primary limb may have a diameter at its proximal end of between about 16 mm and about 36 mm in the expanded configuration and a diameter at its distal end of between about 16 mm and about 25 mm in the expanded configuration. The primary limb may also have a length from its proximal end to its distal end of between about 6 cm and about 15 cm. Desirably, the primary limb includes an annular sleeve at its distal end, the annular sleeve having a substantially uniform diameter. The primary limb may also include securing means at its proximal end for securing the primary limb to the tubular anatomical structure.

The base member may have a first diameter at its proximal end and a second diameter greater than the first diameter at its distal end. In preferred embodiments, the base member may have a diameter at its proximal end of between about 16 mm and about 25 mm in the expanded configuration. The base member may also include an annular sleeve at its proximal end, the annular sleeve having a substantially uniform diameter. Preferably, the annular sleeve has a length between about 2 cm and about 15 cm.

The base member and the primary limb may both consist of a flexible layer which is radially supported along substantially its entire length by an expandable stent. In one embodiment, the expandable stent may be formed from a

high shape-memory material. In another embodiment, the expandable stent may be formed from a low shape-memory material.

In accordance with another embodiment hereof, the base member may include dividing means for forming first and second passageways communicating between the proximal and distal ends of the base member. The dividing means may include a line of stitching joining one surface of the base member to an opposite surface of the base member. Alternatively, the dividing means may include a web of material arranged longitudinally inside the base member and defining a first substantially round aperture adjacent the distal end of the base member and a second substantially round aperture at a spaced distance from the distal end of the base member. Preferred embodiments may further include at least one secondary tubular limb foldable radially between a collapsed configuration and an expanded configuration and having a proximal end and a distal end, and connecting means for connecting the proximal end of the secondary limb to the distal end of the base member.

In accordance with a further embodiment of the present invention, a modular prosthesis for repairing a tubular anatomical structure consists of a base member foldable radially between a collapsed configuration and an expanded configuration and having a proximal end and a distal end, a primary tubular limb foldable radially between a collapsed configuration and an expanded configuration and having a proximal end and a distal end, joining means for intraluminally joining the distal end of the primary limb to the proximal end of the base member, at least one secondary tubular limb foldable radially between a collapsed configuration and an expanded configuration and having a proximal end and a distal end, and connecting means for connecting the proximal end of the secondary limb to the distal end of the base member. The secondary limb may have a substantially uniform diameter of between about 10 mm and about 25 mm in the expanded configuration. Alternatively, the proximal end of the secondary limb may have a diameter which is different than the diameter on its distal end. Preferably, the secondary limb has a length between its proximal end and its distal end of between about 4 cm and about 15 cm.

In this last embodiment, the base member may include a main leg on its proximal end and first and second legs on its distal end. The main leg may extend in an axial direction and have a main bore extending longitudinally therein and defining an inlet on its free end. The first leg may be oriented at a first angle to the axial direction and have a first bore extending longitudinally therein and communicating with the main bore, and may define a first outlet on its free end. The second leg may be oriented at a second angle to the axial direction and have a second bore extending longitudinally therein and communicating with the main bore, and the second leg may define a second outlet on its free end. The first angle may be different than the second angle, but each of the first and second angles are preferably between about 10 degrees and about 60 degrees. Also, the main leg may be oriented in a primary plane, and at least one of the first and second legs may be oriented in a plane different than the primary plane.

In a variant of this last embodiment, the base member may include a crotch defined between the first and second legs, the first leg having a length between the crotch and the first outlet of between about 2 cm and about 15 cm. Preferably, the first leg has a substantially uniform diameter of between about 10 mm and about 25 mm in the expanded configuration, and the second leg has a diameter which decreases in size from the second outlet toward the main leg.

This last embodiment may further include another secondary tubular limb foldable radially between a collapsed configuration and an expanded configuration and having a proximal end and a distal end, and attaching means for attaching the proximal end of the another secondary limb to the distal end of the base member. The another secondary limb may have a length between its proximal end and its distal end of between about 4 cm and about 15 cm, and a substantially uniform diameter of between about 10 mm and about 25 mm in the expanded configuration. Alternatively, the another secondary limb may have a first diameter at its proximal end and a second diameter at its distal end different than the first diameter.

In yet another embodiment of the present invention, a modular prosthesis for repairing a tubular anatomical structure may consist of a base member extending longitudinally between a proximal end defining an inlet and a distal end defining first and second outlets, the base member being foldable radially between a collapsed configuration and an expanded configuration, and a primary tubular limb having a proximal end and a distal end and being foldable radially between a collapsed configuration and an expanded configuration. The distal end of the primary limb in the expanded configuration may be matable in overlapping circumferential engagement with the inlet of the base member when the base member is in the expanded configuration to join the primary limb to the base member. The modular prosthesis may also include at least one secondary tubular limb having a proximal end and a distal end and being foldable radially between a collapsed configuration and an expanded configuration. The proximal end of the at least one secondary limb may be matable in overlapping circumferential engagement with one of the first and second outlets of the base member when the base member is in the expanded configuration to join the at least one secondary limb to the base member. Another secondary tubular limb may also be provided in which its proximal end is matable in overlapping circumferential engagement with another of the first and second outlets of the base member when the base member is in the expanded configuration to join the another secondary limb to the base member.

Another aspect of the present invention provides a prosthesis for repairing a tubular anatomical structure consisting of a hollow tubular body constructed from a woven fabric and having a length defined between a first end and a second end, the first end having a first diameter and the second end having a second diameter, the body having a diameter intermediate the first and second ends which is less than at least one of the first and second diameters. The first diameter may also be less than the second diameter. The first end of the body may have a diameter between about 16 mm and about 25 mm and the second end of the body may have a diameter between about 16 mm and about 36 mm. The diameter of at least a portion of the body may increase in size at an angle of taper between about 2 degrees and about 15 degrees, preferably at an angle of taper of about 4 degrees. The body may also have a length between about 6 cm and about 15 cm. Preferably, the body also includes an annular sleeve integrally formed at one end, the annular sleeve having a substantially uniform diameter.

Preferred embodiments of this aspect of the present invention may further include an expandable stent assembled to the body and radially supporting the body along substantially the entirety of its length. The expandable stent may be assembled in the interior of the body or on the exterior of the body, and may be formed from a high shape-memory material or from a low shape-memory material.

Yet another aspect of the present invention provides a method for repairing a tubular anatomical structure having a proximal branch and a pair of distal branches projecting from the proximal branch at a point of bifurcation. A method in accordance with this aspect of the present invention may include the steps of providing a first tubular limb foldable radially between a collapsed configuration and an expanded configuration and having a proximal end and a distal end, providing a base member foldable radially between a collapsed configuration and an expanded configuration and having an inlet and first and second outlets, and providing a primary tubular limb foldable radially between a collapsed configuration and an expanded configuration and having a proximal end and a distal end. The first limb may be fed in the collapsed configuration through one distal branch until its proximal end is positioned adjacent the point of bifurcation and its distal end is positioned within the one distal branch. The first limb may then be expanded from the collapsed configuration to the expanded configuration whereupon it engages and becomes secured within the one distal branch.

The base member may then be fed in the collapsed configuration through the one distal branch and the first limb until the inlet is positioned in the proximal branch, the first outlet is positioned within the proximal end of the first limb, and the second outlet is at least partially aligned with the other distal branch. The base member may then be expanded from the collapsed configuration to the expanded configuration, whereupon the first outlet engages the proximal end of the first limb in friction fit circumferential contact to join the first outlet of the base member to the first limb.

The primary limb may be fed in the collapsed configuration through one of the distal branches and one of the first and second outlets of the base member until its proximal end is positioned in the proximal branch and its distal end is positioned within the inlet of the base member. The primary limb may then be expanded from the collapsed configuration to the expanded configuration, whereupon its distal end engages the inlet in friction fit circumferential contact to join the primary limb to the inlet of the base member and its proximal end engages and becomes secured within the proximal branch.

Preferred methods may further include the steps of providing a second tubular limb foldable radially between a collapsed configuration and an expanded configuration and having a proximal end and a distal end, feeding the second limb in the collapsed configuration through the other distal branch until its proximal end is positioned within the second outlet of the base member and its distal end is positioned within the other distal branch, and expanding the second limb from the collapsed configuration to the expanded configuration, whereupon its proximal end engages the second outlet of the base member in friction fit circumferential contact to join the second limb to the second outlet of the base member and its distal end engages and becomes secured within the other distal branch. The steps of feeding and expanding the second limb may occur prior to the steps of feeding and expanding the primary limb.

Another method in accordance with the present invention may include the steps of providing a base member foldable radially between a collapsed configuration and an expanded configuration and having an inlet and first and second outlets, and providing a primary tubular limb foldable radially between a collapsed configuration and an expanded configuration and having a proximal end and a distal end. The base member may be fed in the collapsed configuration through one of the distal branches until the inlet is positioned in the proximal branch, the first outlet is positioned within the one distal branch, and the second outlet is at least partially aligned with the other distal branch, and expanded from the collapsed configuration to the expanded configuration, whereupon the first outlet engages and becomes secured within the one distal branch. The primary limb may be fed in the collapsed configuration through one of the distal branches and one of the first and second outlets of the base member until its proximal end is positioned in the proximal branch and its distal end is positioned within the inlet of the base member. The primary limb may be expanded from the collapsed configuration to the expanded configuration, whereupon its distal end engages the inlet in friction fit circumferential contact to join the primary limb to the base member and its proximal end engages and becomes secured within the proximal branch.

This last method may further include the steps of providing a first tubular limb foldable radially between a collapsed configuration and an expanded configuration and having a proximal end and a distal end, feeding the first limb in the collapsed configuration through the other distal branch until its proximal end is positioned within the second outlet of the base member and its distal end is positioned within the other distal branch, and expanding the first limb from the collapsed configuration to the expanded configuration, whereupon its proximal end engages the second outlet of the base member in friction fit circumferential contact to join the first limb to the second outlet of the base member and its distal end engages and becomes secured within the other distal branch.

A still further method for repairing anatomical structures in accordance with the present invention may include the steps of providing a primary tubular limb foldable radially between a collapsed configuration and an expanded configuration and having a proximal end and a distal end, and providing a base member foldable radially between a collapsed configuration and an expanded configuration and having a proximal end and a distal end. The primary limb may be fed in the collapsed configuration through one distal branch until it is positioned entirely in the proximal branch, and expanded from the collapsed configuration to the expanded configuration, whereupon it engages and becomes secured within the proximal branch. The base member may be fed in the collapsed configuration through one distal branch until its proximal end is positioned within the distal end of the primary limb, and expanded from the collapsed configuration to the expanded configuration, whereupon its proximal end engages the distal end of the primary limb in friction fit circumferential contact to join the base member to the primary limb. In preferred methods, the step of feeding the base member may include the step of positioning the base member so that its distal end rests upon the point of bifurcation when the base member is joined to the primary limb.

In a variant of this last method, the base member may include first and second passageways providing communication between its proximal and distal ends, and the method may include the further steps of providing a first tubular limb foldable radially between a collapsed configuration and an expanded configuration and having a proximal end and a distal end, feeding the first limb in the collapsed configuration through one distal branch until its proximal end is positioned within one passageway of the base member and its distal end is positioned within the one distal branch, and expanding the first limb from the collapsed configuration to the expanded configuration, whereupon its proximal end engages the one passageway of the base member in friction

fit circumferential contact to join the first limb to the base member and its distal end engages and becomes secured within the one distal branch. The method may further include the steps of providing a second tubular limb foldable radially between a collapsed configuration and an expanded configuration and having a proximal end and a distal end, feeding the second limb in the collapsed configuration through the other distal branch until its proximal end is positioned within the other passageway of the base member and its distal end is positioned within the other distal branch, and expanding the second limb from the collapsed configuration to the expanded configuration, whereupon its proximal end engages the other passageway of the base member in friction fit circumferential contact to join the second limb to the base member and its distal end engages and becomes secured within the other distal branch.

Yet a further method for repairing a tubular anatomical structure in accordance with the present invention may include the steps of providing a component foldable radially between a collapsed configuration and an expanded configuration and having a proximal end with a first diameter, a distal end with a second diameter, a diameter intermediate its proximal and distal ends which is less than at least one of the first and second diameters. The component may be fed in the collapsed configuration through one distal branch until it is positioned entirely in the proximal branch, and expanded from the collapsed configuration to the expanded configuration, whereupon the component engages and becomes secured within the proximal branch.

In this last method, the component may include first and second passageways providing communication between its proximal and distal ends, and the method may include the added steps of providing a first tubular limb foldable between a collapsed configuration and an expanded configuration and having a proximal end and a distal end, feeding the first limb in the collapsed configuration through one distal branch until its proximal end is positioned within one passageway of the component and its distal end is positioned within the one distal branch, and expanding the first limb from the collapsed configuration to the expanded configuration, whereupon its proximal end engages within the one passageway of the component in friction fit circumferential contact to join the first limb to the component and its distal end engages and becomes secured within the one distal branch. Preferred methods may further include the steps of providing a second tubular limb foldable radially between a collapsed configuration and an expanded configuration and having a proximal end and a distal end, feeding the second limb in the collapsed configuration through the other distal branch until its proximal end is positioned within the other passageway of the component and its distal end is positioned within the other distal branch, and expanding the second limb from the collapsed configuration to the expanded configuration, whereupon its proximal end engages within the other passageway of the component in friction fit circumferential contact to join the second limb to the component and its distal end engages and becomes secured within the other distal branch.

The modular graft system and surgical methods of the present invention overcome many of the difficulties associated with delivering and securing the bifurcated grafts of the prior art. By providing a graft in the form of modular components that can be individually selected and assembled together, the present invention permits more accurate sizing of the graft to the individual patient. Moreover, the modular system forms grafts having a fully supported structure which is much stronger than the prior art grafts and which obviates the prior art procedures in which the graft is secured by hanging at the proximal neck of the aneurysm, which arrangement is prone to acute and chronic failure whereby the graft could become displaced or collapsed. The modular system of the present invention further takes advantage of the flow of blood through the individual components to lock the components to one another, thereby assuring a secure assembly and minimizing the possibility of leakage.

## BRIEF DESCRIPTION OF THE DRAWINGS

A more complete appreciation of the subject matter of the present invention and the various advantages thereof can be realized by reference to the following detailed description, in which reference is made to the accompanying drawings in which:

FIG. **1** is a perspective assembled view of a modular system for forming a bifurcated graft in accordance with one embodiment of the present invention;

FIG. **2** is an exploded, perspective view of the modular system of FIG. **1**, partially broken away to reveal the stent structures in the interior thereof;

FIGS. **3**A–J are highly schematic partial cross-sectional views of an abdominal aortic aneurysm showing the sequence of steps to repair same using the modular system shown in FIG. **1**;

FIG. **4** is a perspective assembled view of a modular system in accordance with an alternate embodiment of the present invention;

FIGS. **5**, **6** and **7** are perspective views of base members for use in connection with modular systems in accordance with still further embodiments of the present invention;

FIG. **8** is a perspective view of a component of a modular system in accordance with yet another embodiment of the present invention;

FIG. **9** is a perspective view of a delivery catheter assembly for use in connection with the modular system shown in FIG. **1**, the sheath of the delivery catheter assembly being in the fully retracted position and being partially broken away to show the interior thereof; and

FIG. **10** is a cross-sectional view of the delivery catheter assembly shown in FIG. **9**, the sheath thereof being in the fully extended position.

## DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

In the detailed description which follows, the features of the present invention will be described in connection with the repair of an abdominal aortic aneurysm. A typical abdominal aortic aneurysm is illustrated in FIGS. **3**A–J, in which the wall of the aorta **200** is weakened and forms a bulge **202** in the region between the renal arteries **204** and the point at which the aorta **200** branches into the right iliac artery **206** and left iliac artery **208**. It will be appreciated, however, that the various features of the present invention may be readily utilized to repair defects in any body lumen which branches into two or more lumens. Indeed, the features of the present invention may be utilized to repair a variety of defects in a body lumen even where the lumen does not have branches associated with it.

Referring to FIGS. **1** and **2**, there is illustrated one preferred embodiment of a modular system **100** for forming a bifurcated graft in accordance with one aspect of the present invention. As used herein, the term "modular" refers to the fact that system **100** includes a number of individual components which may be separately delivered by intralu-

minal techniques to the aneurysm site and then interconnected with one another in situ to form the bifurcated graft. Each of the components of modular system **100** is a fully supported structure which provides sufficient strength to permit the in situ construction of the bifurcated graft. In accordance with one embodiment hereof, modular system **100** includes a primary graft **110**, a base member **112**, and first and second grafts **114** and **116**, respectively, all of which are fabricated as separate components which may be assembled in preselected size combinations depending upon the arterial morphology presented by the patient. Accordingly, each of the various components is preferably provided in a range of sizes sufficient to accommodate the arterial morphology which the surgeon is likely to face in the vast majority of patients.

Primary graft **110** preferably includes a main tapered portion **111** and an annular sleeve **113** having a substantially uniform diameter, tapered portion **111** and sleeve **113** together defining the overall length of primary graft **110** between proximal end **110***a* and distal end **110***b*. As used herein, the term "proximal" refers to the end of a component which is upstream or closest to the heart, and the term "distal" refers to the end of a component which is downstream or farthest away from the heart. Primary graft **110** may be provided in a number of lengths ranging from about 6 cm to about 15 cm in increments of about 10 mm, and in a number of diameters in the expanded condition ranging from about 16 mm to about 36 mm at the proximal end **110***a* and from about 16 mm to about 25 mm at the distal end **110***b*, both in increments of about 2 mm. Preferably, graft **110** is provided in a range of lengths from about 8 cm to about 12 cm at about 10 mm increments, in a range of diameters at proximal end **110***a* from about 24 mm to about 36 mm in increments of about 2 mm in the expanded condition, and with a diameter of about 22 mm in the expanded condition at distal end **110***b*. Furthermore, graft **110** may take the form of a series of two or more grafts which are shorter in length than graft **110** but which can be assembled to one another in succession during the surgical procedure described below to form a primary graft having the desired length.

The tapered portion **111** of primary graft **110** preferably has an angle of taper between about 2 degrees and about 15 degrees from the centerline thereof, with an angle of taper of about 4 degrees being most preferred. It will be appreciated, of course, that the lengths and diameters of primary graft **110** may be provided in wider or more narrow increments depending upon the size variations in the aorta which surgeons experience from patient to patient. Furthermore, the foregoing dimensions are for use in repairing an abdominal aneurysm; the components of a modular system for repairing other body lumens thus may be provided in different size ranges and in different increments.

Primary graft **110** desirably includes a first series of radiomarkers **118** positioned around the periphery of proximal end **110***a*, and a second series of radiomarkers **120** positioned around the periphery of distal end **110***b*. Such radiomarkers are conventional in the art and, when viewed under fluoroscopy, enable the surgeon to identify and properly locate the ends of primary graft **110** during surgical implantation. Thus, radiomarkers **118** and **120** may be formed from biocompatible metals, such as, for example, stainless steel or platinum-iridium, which are radioopaque, or from radioopaque polymers.

Grafts **114** and **116** are similar in construction to primary graft **110**. Thus, grafts **114** and **116** preferably have a generally cylindrical tubular construction with graft **114** having a proximal end **114***a* and a distal end **114***b*, and graft **116** having a proximal end **116***a* and a distal end **116***b*. Grafts **114** and **116** may be provided in a number of lengths ranging from about 4 cm to about 15 cm in increments of about 10 mm, and in a number of diameters in the expanded condition ranging from about 10 mm to about 25 mm in increments of about 2 mm. Grafts **114** and **116** preferably are provided in lengths from about 4 cm to about 8 cm in 10 mm increments, and with diameters in 2 mm increments from about 12 mm to about 16 mm in the expanded configuration. In contrast to the tapered configuration of primary graft **110**, grafts **114** and **116** may have a substantially uniform diameter along their entire lengths between the proximal and distal ends. However, it is contemplated that grafts **114** and **116** may have a tapered configuration similar to that of graft **110**, wherein the diameter of the graft may either increase or decrease from the proximal to the distal end thereof. Such tapered grafts are particularly useful, for example, in those situations where the aneurysmal condition extends from the aorta into the iliac, enabling the graft to have a larger diameter where it will lie in the bulged portion of the iliac and a smaller diameter where it will lie in the normal portion of the iliac.

Grafts **114** and **116** also preferably include a series of radiomarkers at their respective ends. Thus, graft **114** may include a first series of radiomarkers **122** positioned along the periphery of proximal end **114***a* and a second series of radiomarkers **124** positioned along the periphery of distal end **114***b*. Similarly, graft **116** may include one series of radiomarkers **126** positioned along the periphery of proximal end **116***a* and another series of radiomarkers **128** positioned along the periphery of distal end **116***b*.

Base member **112** is a hollow generally Y-shaped structure formed by a frustoconical main body **130** which branches into two legs **132** and **134**. Leg **132** may have a generally cylindrical shape with a substantially uniform diameter from its juncture with main body **130** to the free end thereof. Leg **134**, on the other hand, defines a skirt which gradually increases in diameter from its juncture with main body **130** to its free end. Opposite legs **132** and **134**, main body **130** may include an annular sleeve **131** having a substantially uniform diameter, the free end of which defines an inlet **136** on the proximal end of base member **112**, while outlets **138** and **140** are defined at the free ends of legs **132** and **134**, respectively. Base member **112** may be formed by the same methods, discussed in detail below, which are used to form the taper of primary graft **110**. That is, a tapered tubular "blank" may initially be woven with an annular sleeve **131** formed on one end. Leg **132** may then be created by sewing upwardly from the enlarged end of the tapered portion and parallel to the wall thereof with an overlapping edge stitch. The stitch may then be continued to form the crotch area of base member **112** and then downwardly toward the enlarged end of the tapered portion and away from the wall thereof to form leg **134**. Subsequently, any excess material between legs **132** and **134** may be cut away.

As with grafts **110**, **114** and **116**, base member **112** also may include a series of radiomarkers for identifying its position during surgical implantation. Thus, one series of radiomarkers **142** may be positioned along the periphery of the proximal end of base member **112**, another series of radiomarkers **144** may be positioned along the periphery of the free end of leg **132**, and a further series of radiomarkers **146** may be positioned along the periphery of the free end of leg **134**. Yet another series of radiomarkers **148** may be arranged around the circumference of leg **134** at its juncture with main body **130**. Finally, base member **112** may include

a further single radiomarker **150** spaced distally from radiomarkers **142** in alignment with the side of leg **134** opposite leg **132** for indicating to the surgeon the rotational orientation of base member **112**.

Preferably, base member **112** is also provided in a range of sizes and geometries. In that regard, the various diameters of base member **112** will most preferably be sized relative to the diameters of grafts **110**, **114** and **116** so that the grafts and base member can be joined together with a tight, secure fit. Thus, base members **112** may be provided in which annular sleeve **131** has a diameter in the expanded condition in a range of sizes from about 16 mm to about 25 mm in increments of about 2 mm, with an expanded diameter of about 22 mm being most preferred. Sleeve **131** also may come in a range of lengths from about 2 cm to about 15 cm in increments of about 10 mm. Similarly, leg **132** may have an expanded diameter in a range of sizes from about 10 mm to about 25 mm in increments of about 2 mm, expanded diameters from about 12 mm to about 15 mm being most preferred, and a length in a range of sizes from about 2 cm to about 10 cm in increments of about 10 mm. In a preferred arrangement, leg **134** may be provided with a single diameter at its juncture with main body **130** of basemember **112**, rather than with a range of different diameters. In such event, graft **116** would be provided with a corresponding diameter at its proximal end **116***a*, and may then taper outwardly to the desired diameter at its distal end **116***b*. Alternatively, leg **134** may be provided in a range of diameters at its juncture with main body **130** to correspond to the diameter of graft **116** where a graft **116** having a uniform diameter within a range of diameters is employed.

As noted above, base member **112** may also be provided with different geometries. That is, the angle at which legs **132** and **134** project from the longitudinal centerline C of main body **130** may be varied to accommodate differences in arterial morphology from one patient to the next. Accordingly, base members **112** may be provided such that leg **132** projects from centerline C at one of a number of different angles $\alpha$ ranging from about 10 degrees to about 60 degrees, in increments of about 5 degrees. Similarly, base members **112** may be provided in which leg **134** projects from centerline C at one of a number of different angles $\beta$ ranging from about 10 degrees to about 60 degrees, in increments of about 5 degrees. Legs **132** and **134** need not project at the same angle from longitudinal centerline C. In other words, the angles at which legs **132** and **134** project from main body **130** may be determined independently of one another so as to conform as closely as possible to the arterial geometry of the patient. Moreover, the centerlines of legs **132** and **134** need not lie in the same plane as the centerline C of main body **130**, but may project from centerline C in a third dimension (outwardly from the page) at one of a number of different angles ranging from about 0 degrees to about 90 degrees, in increments of about 5 degrees. While legs **132** and **134** would typically project at the same angle from centerline C in the third dimension, this need not be the case and base members **112** may be provided in which legs **132** and **134** project at different angles from one another in the third dimension.

Each of grafts **110**, **114** and **116** preferably consists of a flexible outer layer **152** which is supported internally along substantially its entire length by an expandable stent **154** which assumes a generally cylindrical or tapered configuration in the expanded condition, depending upon the configuration it is given when initially formed, and which provides the graft with sufficient structural strength to permit the components of modular system **10** to be assembled to one another in situ. In the case of primary graft **110**, stent **154** may protrude beyond the proximal end **110***a* thereof and include one or more barbs **156** for anchoring graft **110** to the wall of aorta **200** to assist in holding modular assembly **100** in place. Alternatively, stent **154** may occupy the exterior of grafts **110**, **114** and **116**, with the flexible layer **152** extending longitudinally therethrough.

Outer layer **152** is preferably formed from a biocompatible material having sufficient strength to withstand the surgical implantation procedure described more fully below and to withstand the blood flow and other biomechanical forces which will be exerted on modular system **100**. Such materials may include, for example, polyester materials, such as DACRON®, polytetrafluoroethylene, expanded polytetrafluoroethylene, polyester materials coated with polytetrafluoroethylene, polyurethane, expanded polyurethane and silicone. Outer layers **152** formed from woven materials are preferred. To reduce the bulk and facilitate the intraluminal delivery of grafts **110**, **114** and **116**, outer layer **152** preferably has a thickness of about 0.1 mm which is about one-third the thickness of conventional graft materials. It will be appreciated, of course, that the present invention can be practiced using materials which are greater than 0.1 mm in thickness, including conventional graft materials.

Methods for forming tubular woven articles having a uniform diameter are well known in the art and are commonly employed in fabricating conventional grafts. Such methods may be utilized to fabricate the outer layer **152** of grafts **114** and **116**. Typical methods make use of a narrow fabric weaving loom where warp threads (i.e., those threads extending in the longitudinal direction of the tube) and weft threads (i.e., those threads extending transverse to the longitudinal direction of the tube) are interlaced with one another. At the weaving station of the loom, the warp threads are fed individually through heddles aligned transverse to the longitudinal direction on one of four or more shafts. The upward and downward movement of the shafts moves a preselected pattern of the warp threads up and then down, two of the shafts moving the warp threads for forming the upper surface of the tube, and two of the shafts moving the warp threads for forming the lower surface of the tube. As the warp threads on one shaft are drawn upwardly and the warp threads on another shaft are drawn downwardly, the weft thread is shuttled in a first direction between those groups of warp threads to weave the upper surface of the tube. The weft thread is then shuttled in a reverse direction between another group of upwardly and downwardly drawn warp threads to weave the lower surface of the tube. The position of the shafts and thus the position of the warp threads is then reversed and the weft thread is again shuttled between the groups of warp threads, the process continuing to weave a tubular shape.

As they approach the weaving station, the warp threads are fed between the fingers of a front reed which align the threads for weaving and which thus determine the ultimate shape of the woven article. For weaving tubular articles having a substantially constant diameter, such as outer layer **152** of grafts **114** and **116**, a conventional front reed which is fixed in place and which has evenly spaced fingers is used to produce constant spacing between the warp threads. Where a tubular article having a gradually increasing or decreasing diameter is desired, however, the conventional reed is replaced with a fan-shaped reed in which the spacing between the fingers is narrow at the bottom and gradually increases toward the top. Such fan-shaped reeds are conventional in the textile industry, and find use for such

applications as weaving tapered flat camera straps. In such processes, the reeds are not held in a fixed position, but rather are moved upward or downward to alter the diameter of the article being woven. Thus, when the fan-shaped reed is gradually moved downward as the weaving of the tube advances, the spacing between the warp threads and, hence, the diameter of the tubular article being woven will gradually be increased. Similarly, when the reed is gradually moved upward as the weaving of the tube advances, the spacing between the warp threads will decrease as will the diameter of the tubular article being woven. The rate of movement of the reed will determine the taper of the article being woven; the faster the reed is moved, the larger the angle of taper, and the slower the reed is moved, the smaller the angle of taper. Moving the reed at a constant rate will produce a constant angle of taper. However, changing the rate of movement of the reed enables tubular articles to be formed with curved or changing angles of taper (as shown in FIGS. **7** and **8**). The upward or downward movement of the reed, and therefore the degree of taper in the woven article, can be controlled in a known fashion by the use of a stepping motor and a system controller.

As the space between the warp threads is increased to weave a tubular article with an increasing diameter, it is desirable to decrease the spacing between the weft threads so as to maintain the structural integrity of the article being woven. This also can be accomplished in a conventional fashion by employing a solenoid-activated mechanism to withdraw the working pawl in the conventional pawl and ratchet fabric take off system from its normal operating position. Operation of the solenoid can also be dictated by the system controller.

Weaving processes employing a movable fan-shaped reed can be employed to form the outer layer **152** for tapered graft **110**. In such process, the front fan-shaped reed of the loom would initially be held in a fixed upper position to weave the substantially uniform diameter tube for annular sleeve **113**. When the annular sleeve **113** reaches the desired length, the front reed would be drawn downward at a rate which would produce the desired angle of taper. The front reed would continue to be drawn downward as the weaving process continues until a layer **152** having the desired tubular configuration has been formed.

Stent **154** may be formed from a wire or the like of a low shape-memory material which has been bent back and forth in a curved pattern in the longitudinal direction of the graft and then wrapped in a circumferential direction transverse to the longitudinal direction to form one or more loops of a predetermined circumference. As used herein, the term "low shape-memory material" refers to a material that, once deformed from an initial shape to a subsequent shape, will tend to maintain the subsequent shape and not return to the initial shape. Such materials preferably include biocompatible metals, including, for example, stainless steel, titanium, tantalum, gold, platinum, copper and the like, as well as alloys of these metals. Biocompatible low shape-memory plastics may also be used to form stent **154**. Alternatively, stent **154** may be formed from a high shape-memory plastic or alloy, such as nitinol, which automatically transforms from one shape to another shape as its temperature passes through a critical point. Whether stent **154** is formed from a low shape-memory material or from a high shape-memory material is not critical, and impacts on the present invention predominantly in terms of the technique used to intraluminally deliver the components of modular system **100** to the aneurysm site and fix same in place. The structure of preferred stents **154** and methods for forming same are disclosed in commonly assigned U.S. patent application Ser. No. 08/353,066 entitled "High Hoop Strength Intraluminal Stent", the disclosure of which is incorporated by reference herein.

Base member **112** is similar in construction to grafts **110**, **114** and **116**, and includes a flexible outer layer **160** which is ordinarily formed from the same materials as outer layer **152**. An expandable generally Y-shaped stent **162** internally supports outer layer **160** along substantially its entire length, providing structural strength thereto, and is ordinarily formed from the same materials and by the same methods as stent **154**. As with grafts **110**, **114** and **116**, base member **112** may be constructed with stent **162** on the exterior and flexible layer **160** arranged interior thereof.

Grafts **110**, **114** and **116** and base member **112** are each radially expandable from a collapsed condition in which the circumferences thereof are minimized so that the components can be delivered to the site of the aortic aneurysm intraluminally, to an expanded condition in which the circumference of each of the components approaches a predetermined maximum circumference. As will be described more fully below, each component is normally held in the collapsed condition by the outer sheath of a catheter during intraluminal delivery. Once properly located, the component is deployed from the catheter and radially expanded until its circumference firmly contacts the interior wall of either the artery in which it is situated or the component to which it is being connected to hold the graft in this implanted location.

Once the proper sizes for the various components of modular system **100** have been selected, the components are preferably preloaded into one or more disposable delivery catheter assemblies which then may be used by the surgeon to intraluminally introduce the components into the patient and to assemble same to one another in the form of a bifurcated graft. One such delivery catheter assembly **300** is shown in FIGS. **9–10**. Delivery catheter assembly **300** includes an elongated tubular outer sheath **302** formed from a conventional polymer which is sufficiently flexible that it will readily bend as catheter assembly **300** is fed through the arterial path during the intraluminal surgical procedure. Typical materials for forming sheath **302** include, for example, nylon, teflon polytetrafluoroethylene, polyethylene and the like. The forward end **302***a* of sheath **302** may include a radiomarker **304** for readily identifying and locating end **302***a* under fluoroscopy. Radiomarker **304** may take the form of an annular ring formed from a metal, such as stainless steel or platinum-iridium, or a radioopaque polymer, or may consist of any radioopaque material applied to the end **302***a* of sheath **302**. At its rearward end **302***b*, sheath **302** may include a conventional T-handle **306** having finger grips **308** and a hollow stem **310**.

An inner tubular member **312** is arranged in sheath **302** for slidable longitudinal movement with respect thereto. Tubular member **312** defines a continuous internal passageway **313** through delivery catheter **300** so that the delivery catheter can be assembled onto and follow a guidewire during the intraluminal delivery procedure. In that regard, tubular member **312** may be formed from any biocompatible material which resists kinking. In a preferred arrangement, however, tubular member **312** includes a coiled, spring-like wire **314** which is flexible, yet which has sufficient radial strength to resist collapsing due to the forces exerted by the components of modular system **100** when they are loaded in delivery catheter **300**. In a highly preferred arrangement, the coil **314** may be surrounded by a thin-walled polymer tube **316** or coated with an impervious polymer layer (not shown) so that medications, dyes and the like may be supplied through passageway **313** to the abdominal aorta repair site.

At one end of coil **314**, tubular member **312** includes a tip **318** which may be formed from a biocompatible polymer, such as polyurethane, teflon polytetrafluoroethylene, nylon or the like, with a conventional radioopaque marker (not shown) formed or assembled thereon. Tip **318** preferably has an outer diameter which is larger than the inner diameter of sheath **302** so that tip **318** cannot be drawn into sheath **302** as the sheath and tubular member **312** are moved relative to one another. The forward end of tip **318** preferably has a smoothly curved surface **320** to facilitate the forward movement of delivery catheter assembly **300** through the arterial system. At its rearward end, tip **318** may include a reduced diameter portion **322** sized to fit within the sheath **302** so as to axially align tip **318** with sheath **302** in the mated condition and seal the end **302***a* of the sheath. A bore **324** in tip **318** communicates with the passageway **313** in tubular member **312** to enable a guidewire, medication, dye and the like to exit from delivery catheter assembly **300**.

At the opposite end of coil **314**, tubular member **312** may include a stabilizer tube **326** which extends outwardly of sheath **302** through the hollow stem **310** of T-handle **306**. Stabilizer tube **326** may be formed from any biocompatible material, including polymers such as polyurethane, teflon polytetrafluoroethylene and nylon, and metals, such as stainless steel. A thumbscrew **328** in T-handle **306** may be actuated to engage stabilizer tube **326**, thereby locking tubular member **332** in place with respect to sheath **302**. Exterior of sheath **302**, stabilizer tube **326** may be fitted with a conventional hand grip **330** and any number of conventional accessories, such as the Y-connector **332**, hemostasis valve **334** and stopcock **336** illustrated in FIG. **9**.

A cylindrical spacer **331** formed on tubular member **312** at a spaced distance from the rearward end of tip **318** defines a first annular cavity **333** within sheath **302** for holding and delivering the first component of modular system **100** to be deployed during the surgical procedure described below, in this case graft **114**. Spacer **331** may also be formed from any biocompatible material, including polyurethane, teflon polytetrafluoroethylene, nylon and stainless steel, and preferably includes a radiomarker (not shown) so that its position can be identified by fluoroscopy during the surgical procedure. The length of cavity **333** will depend upon the length of the particular component of modular system **100** to be assembled therein. Thus, cavity **333** preferably will be sufficiently long to accommodate the component, but not so long that there is a substantial unsupported gap between the end of the component and either tip **318** or spacer **331** which may permit sheath **302** to kink as a result of the axial forces applied to feed delivery catheter assembly **300** through the arterial system.

A second spacer **335** having generally the same construction as spacer **331** is formed on tubular member **312** at a spaced distance from the first spacer **331**, thus defining a second annular cavity **337** within sheath **302** for holding and delivering the second component of modular system **100** to be deployed during the surgical procedure, in this case base member **112**. The length of cavity **337** will be sufficient to accommodate base member **112**, but not so long that there is a significant unsupported gap between base member **112** and either spacer **331** or spacer **335**.

Delivery catheter assembly **300** further includes a coiled, spring-like wire **340** assembled in sheath **302** between spacer **335** and the end of stabilizer tube **326**. Coil **340** radially supports sheath **302** to prevent the kinking of same and provides a structure for transferring the axial load applied through T-handle **306** to spacers **335** and **331**, while at the same time not detracting from the overall flexibility of delivery catheter assembly **300**.

A method for introducing and assembling the various components of modular system **100** to repair an abdominal aortic aneurysm will now be described with reference to FIGS. **3A–J**. The described method assumes that the stents **154** within grafts **110**, **114** and **116** and the stent **162** within base member **112** are formed from a memory metal, such that the stents, and hence each of the components, will radially expand automatically as their temperature reaches the transition temperature for the memory metal following deployment within the body. From the method described hereinafter, methods employing balloon expansion techniques for introducing and assembling the components of a modular system **100** in which stents **154** and **162** are formed from low shape-memory materials will be readily apparent to one skilled in the art. Accordingly, a detailed description of such methods is not provided herein.

Thus, in a repair method of the present invention, an arteriotomy is initially performed on the right leg and, under conventional fluoroscopic guidance techniques, a first guidewire **400** is introduced through the right femoral artery (not shown) and right iliac **206** into the aorta **200**. Delivery catheter assembly **300** containing in succession graft **114** and base member **112** may then be assembled on guidewire **400**, the guidewire being threaded through passageway **313** in tubular member **312** and advanced under fluoroscopic guidance until the end **302***a* of sheath **302** is positioned adjacent the junction of right iliac **206** and aorta **200**, as shown in FIG. **3A**. At this point, thumbscrew **328** may be loosened and T-handle **306** of delivery catheter assembly **300** pulled backward to partially retract sheath **302** with respect to tubular member **312**, thereby exposing the proximal end **114***a* of graft **114** as illustrated in FIG. **3B**. Sheath **302** may then be retracted further to the position illustrated in FIG. **3C** wherein the end **302***a* thereof is aligned with spacer **331**, at which point the first annular cavity **333** will be completely open and the entirety of graft **114** will be exposed. With sheath **302** no longer insulating graft **114** and retaining it in the collapsed condition, graft **114** will expand radially as its temperature increases through the transition temperature of the memory metal forming the stent **154** therein. This radial expansion will continue until the outer layer **152** of graft **114** firmly engages the interior wall of iliac **206** to hold graft **114** in this implanted location.

Following deployment of graft **114**, thumbscrew **328** may be tightened to lock sheath **302** relative to tubular member **312** and delivery catheter assembly **300** may be advanced as a unit into the base of aneurysm **202**, as shown in FIG. **3D**, until the radiomarkers **144** on leg **132** of base member **112** are aligned within the proximal end **114***a* of graft **114**, at a spaced distance below the radiomarkers **122**. This distance should be such as to provide a sufficient overlap between the proximal end **114***a* of graft **114** and the free end of leg **132** that a secure connection will be formed between these members. Once properly positioned, thumbscrew **328** may be loosened and the outer sheath **302** of delivery catheter assembly **300** retracted relative to tubular member **312** to expose sleeve **131** on the proximal end of base member **112**. At this point, the surgeon may look for the single radiomarker **150** just inwardly of radiomarkers **142** to assure that leg **134** of base member **112** is in alignment with left iliac **208**. If leg **134** is not properly aligned, delivery catheter assembly **300** may be rotated until such alignment is achieved. With base member **112** properly positioned, sheath **302** may be retracted further as shown in FIG. **3E** until the end **302***a* thereof is aligned with spacer **335**, whereupon the second annular cavity **337** will be completely open and the entirety of base member **112** will be exposed. Again, without

sheath 302 retaining it in the collapsed condition, base member 112 will expand radially until the free end of leg 132 contacts and firmly engages the interior wall on the proximal end 114*a* of graft 114 in overlapping relationship. Forming leg 132 of base member 112 with a diameter in the fully expanded condition which is larger than the fully expanded diameter of graft 114 will assure that the foregoing assembly procedure securely locks base member 112 and graft 114 together and forms a seal which prevents the leakage of blood from therebetween.

With graft 114 and base member 112 deployed and assembled together, tubular member 312 may be retracted with respect to sheath 302 until the reduced portion 322 of tip 318 is positioned within the end 302*a* of sheath 302. Thumbscrew 328 may then be tightened to lock these two elements together and the entire delivery catheter assembly 300 may be withdrawn from the patient, with guidewire 400 being retracted into right iliac 206 and temporarily left in place therein. A second arteriotomy may then be performed on the left leg of the patient and, again under fluoroscopic guidance, a second guidewire 410 may be introduced up through the left femoral artery (not shown), through the left iliac 208, into base member 112 through the outlet 140 defined at the free end of leg 134, and finally out through the inlet 136 defined at the free end of sleeve 131. With guidewire 410 in place, guidewire 400 may be fully withdrawn from the patient. A second delivery catheter assembly 500 containing in succession grafts 116 and 110 may then be advanced over guidewire 410 through the left femoral artery and left iliac 208 until the tip 518 thereof is positioned within leg 134 of base member 112, with radiomarkers 126 on the proximal end 116*a* of graft 116 located a spaced distance above radiomarkers 148 on base member 112 at the juncture of leg 134 and main body 130, all as illustrated in FIG. 3F. When delivery catheter assembly 500 has been properly positioned, the thumbscrew thereon (not shown) may be loosened and sheath 502 partially retracted with respect to tubular member 512, thereby exposing the proximal end 116*a* of graft 116. With sheath 502 no longer holding the proximal end 116*a* of graft 116 in the collapsed condition, the proximal end will begin to expand radially until it contacts and firmly engages the inner wall of base member 112 at the juncture between main body 130 and leg 134. Again, a secure leakproof assembly of graft 116 to base member 112 can be obtained by assuring that the diameter of graft 116 in the fully expanded condition is greater than the diameter of base member 112 at the juncture between main body 130 and leg 134, and that a sufficient portion of the proximal end 116*a* of graft 116 is located above this juncture. The remainder of graft 116 may then be deployed as shown in FIG. 3H by retracting sheath 502 further until the end 502*a* thereof is aligned with spacer 530.

Once graft 116 has been deployed, guidewire 410 may be advanced until the end thereof is positioned above the renal arteries 204. The thumbscrew on delivery catheter assembly 500 may be tightened to lock sheath 502 relative to tubular member 512 and the delivery catheter assembly may then be advanced over guidewire 410 to the position shown in FIG. 3H, wherein the radiomarkers 120 on the distal end 110*b* of graft 110 are positioned within sleeve 131 of base member 112, but at a spaced distance below radiomarkers 142. When primary graft 110 has been properly located with respect to base member 112, i.e., with a sufficient overlap between the distal end 110*b* of graft 110 and the proximal end of base member 112, the thumbscrew on delivery catheter assembly 500 may be loosened and sheath 502 retracted relative to tubular member 512 to expose the proximal end 110*a* of graft 110. As illustrated in FIG. 3I, with sheath 502 no longer holding it in the collapsed condition, the proximal end 110*a* of graft 110 will expand radially until the outer layer thereof firmly engages the interior wall of aorta 200. This radial expansion will also cause the barbs 156 on the proximal end of graft 110 to contact the inner wall of aorta 200. Tightening the thumbscrew thereof and then tugging slightly on delivery catheter assembly 500 will assure that barbs 156 grab into the inner wall of aorta 200 to assist in holding primary graft 110 and, hence, the proximal end of modular system 100 in place. With barbs 156 securely engaged, the thumbscrew may be loosened and sheath 502 retracted relative to tubular member 512 until the tip 502*a* of the sheath is aligned with spacer 534 to expose and deploy the remainder of primary graft 110. As primary graft 110 is fully deployed, the distal end 110*b* thereof will expand radially until it firmly engages the interior wall of sleeve 131, securely locking primary graft 110 to base member 112 in a leakproof arrangement. Tubular member 512 may then be retracted relative to sheath 502 until the reduced diameter portion 522 of its tip 518 is positioned within the end 502*a* of the sheath. Tubular member 512 may then be locked to sheath 502 by tightening the thumbscrew of delivery catheter assembly 500, and the entire assembly may be withdrawn from the patient. Subsequently, guidewire 410 may be withdrawn from the patient and the arteriotomies sutured.

Once deployed and assembled together according to the foregoing procedure, the components of modular system 100 form a bifurcated graft which is fully self supporting. That is, as a result of its bottom-up assembly, the biomechanical forces exerted on the graft, particularly from the flow of blood, are supported along its entire length in a columnar fashion.

It will be appreciated, of course, that variations in the foregoing procedure can be made without departing from the scope of the present invention. For example, delivery catheter assembly 300 may be fabricated with three spacers defining three annular cavities in succession, with graft 114 loaded in the first annular cavity, base member 112 loaded in the second annular cavity and primary graft 110 loaded in the third annular cavity. In such event, graft 114 and base member 112 may be deployed in succession as described above, following which the delivery catheter assembly may be advanced to deploy primary graft 110. Subsequently, graft 116 would be deployed and assembled to base member 112 as described above utilizing a second delivery catheter assembly having only one spacer defining a single annular cavity for holding graft 116.

Other variations from the foregoing method are also possible. In this regard, rather than relying merely upon the outward radial forces exerted by the expanding stent structures of grafts 110 and 116 and base member 112 to securely lock the components together, the appropriate ends of these components may be provided with mechanical structures, such as barbs, sutures and the like, to assure that the components are securely held together.

By changing the configuration of the various components of the modular system, still other variations in the surgical procedure are possible. Thus, referring to FIG. 4, the modular system may include a base member 550 having an integral elongated leg 552. Leg 552 would typically be formed with a substantially uniform diameter and a sufficient length that at least the distal end 554 thereof will securely engage right iliac 206 upon the deployment of base member 550, thereby eliminating the need to deploy a separate graft in right iliac 206 and connect the base member thereto, as in the case with graft 114 and base member 112

described above. As a result, the use of base member 550 results in a simpler surgical procedure while maintaining substantially all of the advantages associated with the modular system 100 of the present invention.

Furthermore, the base member need not have integrally formed legs depending distally therefrom. For example, in accordance with another embodiment of the present invention, the modular system may include a base member 600 such as shown in FIG. 5. Base member 600 has a generally frustoconical main body 602 which gradually decreases in diameter from the distal end 600*b* of the base member to its juncture with an annular sleeve 604. Sleeve 604 has a substantially uniform diameter until its terminus at the proximal end 600*a* of base member 600. The main body 602 of base member 600 is divided into two portions 606 and 608 by a web 610 which extends from the distal end 600*b* of the base member to the juncture between main body 602 and sleeve 604. Web 610 is connected within base member 600, such as by sewing, heat welding or the like, so as to define a substantially circular opening 612 on one side of the distal end 600*b* of base member 600, and another substantially circular opening 614 on the other side of base member 600 at the juncture between main body 602 and annular sleeve 604. The diameter of opening 612 is preferably large enough to readily accept the proximal end 116*a* of graft 116, but not so large as to interfere with the insertion of the proximal end 114*a* of graft 114 into the remaining crescent-shaped opening 616 at the distal end 600*b* of base member 600. Hence, the diameter of opening 612 is preferably between about one half and three quarters of the diameter of base member 600 at its distal end. As for opening 614, it preferably has a diameter which is smaller than the fully expanded diameter of graft 114 at its proximal end 114*a*.

As with the components of modular system 100 described above, base member 600 preferably consists of a flexible outer layer 618 which is supported internally along substantially its entire length by an expandable stent 620. In a preferred arrangement, web 610 is connected within base member 600 after stent 620 has been placed within outer layer 618.

Base member 600 may also be provided with a plurality of radiomarkers for locating the various regions thereof under fluoroscopy. Thus, base member 600 may include one series of radiomarkers 619 around the periphery of proximal end 600*a*, another series of radiomarkers 621 around the periphery of distal end 600*b*, and another series of radiomarkers 622 formed around the periphery of base member 600 at the juncture between main body 602 and annular sleeve 604. A further single radiomarker 624 may be positioned distally of radiomarkers 622 in alignment with the side of base member 600 opposite opening 614 for indicating the rotational orientation of the base member.

The procedure for implanting and assembling a modular system incorporating base member 600 is different from that described above where the modular system utilizes base member 112. More particularly, rather than deploying and assembling the components from the bottom up as described above, when a base member 600 is utilized the components are deployed and assembled from the top down. That is, the primary graft 110 would be the first component deployed followed by base member 600. In this procedure, however, rather than inserting and expanding the distal end 110*b* of primary graft 110 within the proximal end of the base member to join these components together, just the opposite procedure is performed. In other words, once primary graft 110 has been deployed, base member 600 would be deployed so that its proximal end 600*a* is inserted into and expands within the distal end 110*b* of primary graft 110. Subsequently, graft 116 may be fed upwardly until its proximal end 116*a* enters base member 600 through opening 612. With the proximal end 116*a* of graft 116 positioned at a spaced distance above opening 612 (as determined by radiomarkers appropriately placed on the components), graft 116 may be deployed whereupon it will become securely locked within portion 608 of base member 600, with the substantially circular periphery of graft 116 sealing against the substantially circular periphery of opening 612 to prevent the leakage of blood therebetween. As it radially expands, the distal end 116*b* of graft 116 will engage and become secured within left iliac 208. Graft 110, base member 600 and graft 116 may be deployed in succession from a single delivery catheter assembly similar in construction to delivery catheter assembly 300, yet having a series of three annular cavities. A second delivery catheter assembly may be fed through crescent-shaped opening 616 in base member 600 and then upwardly therefrom to position the proximal end 114*a* of graft 114 at a spaced distance above opening 614 (also as determined by appropriately placed radiomarkers). Upon deployment of graft 114 in this position, the substantially circular periphery thereof will firmly engage the substantially circular periphery of opening 614 to similarly seal against the leakage of blood from therebetween. The distal end 114*b* of graft 114, as it radially expands, will engage and become secured within right iliac 206.

In a variant of the foregoing embodiment, the base member may be formed with the general shape of base member 600, but without the internal web 610. A base member 650 in accordance with this embodiment is illustrated in FIG. 6. Base member 650 is intended to be used in those situations in which the modular system is to be assembled with no iliac grafts 114 and 116. Thus, the modular system would include primary graft 110 and base member 650 which may be deployed either as described immediately above in connection with base member 600 (i.e., primary graft 110 first followed by base member 650), or as described previously in connection with base member 112 (i.e., base member 650 first followed by primary graft 110). However, in positioning base member 650, the surgeon would ensure not only that the proximal end 650*a* of base member 650 will overlap with the distal end 110*b* of graft 110, but also that the distal end 650*b* of base member 650 will lie against the apex between iliacs 206 and 208, whereby the arterial wall at the apex may support the modular system in its fully deployed and assembled condition. In this scenario, blood flow into graft 110 and through base member 650 will divide at the apex as it exits from the distal end 650*b* of the base member and will flow into both the right iliac 206 and left iliac 208.

A still further embodiment of a base member 700 in accordance with the present invention is shown in FIG. 7. In one region 702 extending from proximal end 700*a* along a major portion of its length, base member 700 has a substantially uniform diameter. The diameter of base member 700 then gradually increases in a second region 704 thereof until its terminus at distal end 700*b*. Tapered region 704 may be formed by the same methods used to form the taper of primary graft 110, as discussed more fully above.

Base member 700 further includes a stitch line 706 which extends in the longitudinal direction thereof within region 702, the stitch line joining the outer layer 708 on the diametrically opposed surfaces of base member 700 to define two tubular channels 710 and 712 intermediate proxi-

mal end 700a and distal end 700b. As with the other components of the modular systems described above, the outer layer 708 of base member 700 is supported internally along substantially its entire length by an expandable stent 714. In that regard, stent 714 may consist of an assembly of several members which independently support tapered region 704, tubular channels 710 and 712, and the proximal end of base member 700. Base member 700 may also be provided with radiomarkers, including one series of radiomarkers 716 formed around the periphery of proximal end 700a, another series of radiomarkers 718 formed around the periphery of distal end 700b, and another series of radiomarkers 720 formed around the periphery of the base member at the distal end of stitch line 706. In addition, base member 700 may include a further single radiomarker 722 spaced distally of radiomarkers 716 in alignment with the side of tubular channel 712 opposite tubular channel 710 for indicating the rotational orientation of the base member.

In a variant of this embodiment, tubular channels 710 and 712 may consist of tubes of substantially uniform diameter which are independent of one another. Such embodiment would look similar to base member 700 as illustrated in FIG. 7, but would have an elongated through hole in place of stitch line 706. Such embodiment may be formed, for example, from two devices having a tapered region (as at 704) and two tubular legs extending from the tapered region, one device being inverted relative to the other and the devices being joined to one another at their tubular legs.

One procedure for implanting and assembling a modular system incorporating base member 700 may be similar to that described above in connection with base member 600. That is, the primary graft 110 would be deployed first, following which base member 700 may be deployed with its proximal end 700a inserted into and expanded within the distal end 110b of primary graft 110. Graft 114 may then be fed upwardly until its proximal end 114a resides within tubular channel 710 at a spaced distance above radiomarkers 720. Upon its deployment, the proximal end 114a of graft 114 will become securely locked within tubular channel 710 and the distal end 114b thereof will engage and become secured within right iliac 206. Graft 116 may then be fed upwardly until its proximal end 116a lies within tubular channel 712 at a spaced distance above radiomarkers 720. Upon deployment of graft 116, the proximal end 116a thereof will become securely locked within tubular channel 712 and the distal end 116b thereof will engage and become secured within left iliac 208. It will be appreciated from the foregoing that graft 110, base member 700 and graft 114 may be deployed in succession from a first delivery catheter assembly, with graft 116 being deployed from a second delivery catheter assembly. In an alternate procedure employing base member 700, the base member may be deployed first, followed in succession by grafts 110, 114 and 116.

In a variant of the foregoing embodiment, base member 700 and graft 110 may be combined as a single component 750, illustrated in FIG. 8. Component 750 thus may include a bottom portion 752 which has substantially the same structure as base member 700 described above, including a region 754 having a substantially uniform diameter, a region 756 which gradually increases in diameter as it approaches the distal end 750b of component 750, and a stitch line 758 which defines two tubular channels 760 and 762 within component 750. At its upper end, component 750 includes an integrally formed region 764 which begins with a substantially uniform diameter and which gradually increases in diameter as it approaches the proximal end 750a thereof. Forming portions 752 and 764 as a single integral unit thus eliminates the need to deploy a separate graft 110 within aorta 200 and connect the base member thereto. As a result, modular systems incorporating component 750 provide all of the advantages of the present invention while allowing for a simpler surgical procedure.

Although the invention herein has been described with reference to particular embodiments, it is to be understood that these embodiments are merely illustrative of the principles and applications of the present invention. It is therefore to be understood that numerous modifications may be made to the illustrative embodiments and that other arrangements may be devised without departing from the spirit and scope of the present invention as defined by the appended claims.

We claim:

1. A method for repairing a tubular anatomical structure having a proximal branch and a pair of distal branches projecting from said proximal branch at a point of bifurcation, said method comprising the steps of:

providing a first tubular limb foldable radially between a collapsed configuration and an expanded configuration and having a proximal end and a distal end,

providing a base member foldable radially between a collapsed configuration and an expanded configuration and having an inlet and first and second outlets,

providing a primary tubular limb foldable radially between a collapsed configuration and an expanded configuration and having a proximal end and a distal end,

feeding said first limb in said collapsed configuration through one of said distal branches until said proximal end of said first limb is positioned adjacent said point of bifurcation, and said distal end of said first limb is positioned within said one of said distal branches,

expanding said first limb from said collapsed configuration to said expanded configuration whereupon said first limb engages and becomes secured within said one of said distal branches,

feeding said base member in said collapsed configuration through said one of said distal branches and said first limb until said inlet is positioned in said proximal branch, said first outlet is positioned within said proximal end of said first limb, and said second outlet is at least partially aligned with another one of said distal branches,

expanding said base member from said collapsed configuration to said expanded configuration, whereupon said first outlet engages said proximal end of said first limb in friction fit circumferential contact to join said first outlet of said base member to said first limb,

feeding said primary limb in said collapsed configuration through one of said distal branches and one of said first and second outlets of said base member until said proximal end of said primary limb is positioned in said proximal branch and said distal end of said primary limb is positioned within said inlet of said base member, and

expanding said primary limb from said collapsed configuration to said expanded configuration, whereupon said distal end of said primary limb engages said inlet in friction fit circumferential contact to join said primary limb to said inlet of said base member and said proximal end of said primary limb engages and becomes secured within said proximal branch.

2. The method as claimed in claim 1, further comprising the steps of:

providing a second tubular limb foldable radially between a collapsed configuration and an expanded configuration and having a proximal end and a distal end,

feeding said second limb in said collapsed configuration through said another one of said distal branches until said proximal end of said second limb is positioned within said second outlet of said base member and said distal end of said second limb is positioned within said another one of said distal branches, and

expanding said second limb from said collapsed configuration to said expanded configuration, whereupon said proximal end of said second limb engages said second outlet of said base member in friction fit circumferential contact to join said second limb to said second outlet of said base member and said distal end of said second limb engages and becomes secured within said another one of said distal branches.

3. The method as claimed in claim 2, wherein said steps of feeding and expanding said second limb occur prior to said steps of feeding and expanding said primary limb.

4. A method for repairing a tubular anatomical structure having a proximal branch and a pair of distal branches projecting from said proximal branch at a point of bifurcation, said method comprising the steps of:

providing a base member foldable radially between a collapsed configuration and an expanded configuration and having an inlet and first and second outlets,

providing a primary tubular limb foldable radially between a collapsed configuration and an expanded configuration and having a proximal end and a distal end,

feeding said base member in said collapsed configuration through one of said distal branches until said inlet is positioned in said proximal branch, said first outlet is positioned within said one of said distal branches, and said second outlet is at least partially aligned with another one of said distal branches,

expanding said base member from said collapsed configuration to said expanded configuration, whereupon said first outlet engages and becomes secured within said one of said distal branches,

feeding said primary limb in said collapsed configuration through one of said distal branches and one of said first and second outlets of said base member until said proximal end of said primary limb is positioned in said proximal branch and said distal end of said primary limb is positioned within said inlet of said base member, and

expanding said primary limb from said collapsed configuration to said expanded configuration, whereupon said distal end of said primary limb engages said inlet in friction fit circumferential contact to join said primary limb to said base member and said proximal end of said primary limb engages and becomes secured within said proximal branch.

5. The method as claimed in claim 4, further comprising the steps of:

providing a first tubular limb foldable radially between a collapsed configuration and an expanded configuration and having a proximal end and a distal end,

feeding said first limb in said collapsed configuration through said another one of said distal branches until said proximal end of said first limb is positioned within said second outlet of said base member and said distal end of said first limb is positioned within said another one of said distal branches, and

expanding said first limb from said collapsed configuration to said expanded configuration, whereupon said proximal end of said first limb engages said second outlet of said base member in friction fit circumferential contact to join said first limb to said second outlet of said base member and said distal end of said first limb engages and becomes secured within said another one of said distal branches.

6. A method for repairing a tubular anatomical structure having a proximal branch and a pair of distal branches projecting from said proximal branch at a point of bifurcation, said method comprising the steps of:

providing a primary tubular limb foldable radially between a collapsed configuration and an expanded configuration and having a proximal end and a distal end;

providing a base member foldable radially between a collapsed configuration and an expanded configuration and having a proximal end and a distal end;

feeding said primary limb in said collapsed configuration through one of said distal branches until said primary limb is positioned entirely in said proximal branch;

expanding said primary limb from said collapsed configuration to said expanded configuration, whereupon said primary limb engages and becomes secured within said proximal branch;

feeding said base member in said collapsed configuration through one of said distal branches until said proximal end of said base member is positioned within said distal end of primary limb and said distal end of said base member rests upon said point of bifurcation; and

expanding said base member from said collapsed configuration to said expanded configuration, whereupon said proximal end of said base member engages said distal end of said primary limb in friction fit circumferential contact to join said base member to said primary limb.

7. A method for repairing a tubular anatomical structure having a proximal branch and a pair of distal branches projecting from said proximal branch at a point of bifurcation, said method comprising the steps of:

providing a primary tubular limb foldable radially between a collapsed configuration and an expanded configuration and having a proximal end and a distal end;

providing a base member foldable radially between a collapsed configuration and an expanded configuration and having a proximal end, a distal end and first and second passageways providing communication between said proximal and distal ends;

providing a first tubular limb foldable radially between a collapsed configuration and an expanded configuration and having a proximal end and a distal end;

feeding said primary limb in said collapsed configuration through one of said distal branches until said primary limb is positioned entirely in said proximal branch;

expanding said primary limb from said collapsed configuration to said expanded configuration, whereupon said primary limb engages and becomes secured within said proximal branch;

feeding said base member in said collapsed configuration through one of said distal branches until said proximal

end of said base member is positioned within said distal end of said primary limb;

expanding said base member from said collapsed configuration to said expanded configuration, whereupon said proximal end of said base member engages said distal end of said primary limb in friction fit circumferential contact to join said base member to said primary limb;

feeding said first limb in said collapsed configuration through one of said distal branches until said proximal end of said first limb is positioned within one of said first and second passageways of said base member and said distal end of said first limb is positioned within said one distal branch; and

expanding said first limb from said collapsed configuration to said expanded configuration, whereupon said proximal end of said first limb engages said one of said first and second passageways of said base member in friction fit circumferential contact to join said first limb to said base member and said distal end of said first limb engages and becomes secured within said one distal branch.

8. The method as claimed in claim 7, further comprising the steps of:

providing a second tubular limb foldable radially between a collapsed configuration and an expanded configuration and having a proximal end and a distal end,

feeding said second limb in said collapsed configuration through another one of said distal branches until said proximal end of said second limb is positioned within another one of said first and second passageways of said base member and said distal end of said second limb is positioned within said another one of said distal branches, and

expanding said second limb from said collapsed configuration to said expanded configuration, whereupon said proximal end of said second limb engages said another one of said first and second passageways of said base member in friction fit circumferential contact to join said second limb to said base member and said distal end of said second limb engages and becomes secured within said another one of said distal branches.

* * * * *

# UNITED STATES PATENT AND TRADEMARK OFFICE
# CERTIFICATE OF CORRECTION

**PATENT NO.** : 5,676,696

**DATED** : October 14, 1997

**INVENTOR(S)** : Marcade

**It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:**

Column 7, line 22, after "second diameter," insert --and--.

Column 15, line 27, "332" should read --312--.

Signed and Sealed this

Seventeenth Day of February, 1998

*Attest:*

BRUCE LEHMAN

*Attesting Officer*

*Commissioner of Patents and Trademarks*

US005617878A

# United States Patent [19]

Taheri

[11] Patent Number: 5,617,878

[45] Date of Patent: Apr. 8, 1997

[54] **STENT AND METHOD FOR TREATMENT OF AORTIC OCCLUSIVE DISEASE**

[76] Inventor: **Syde A. Taheri**, 268 Dan-Troy, Williamsville, N.Y. 14221

[21] Appl. No.: **656,671**

[22] Filed: **May 31, 1996**

[51] **Int. Cl.**[6] ..... **A61B 19/00**

[52] **U.S. Cl.** ..... **128/898**; 606/198; 623/1

[58] **Field of Search** ..... 128/898; 623/1, 623/11, 12; 606/1, 159, 191–200; 604/96–104

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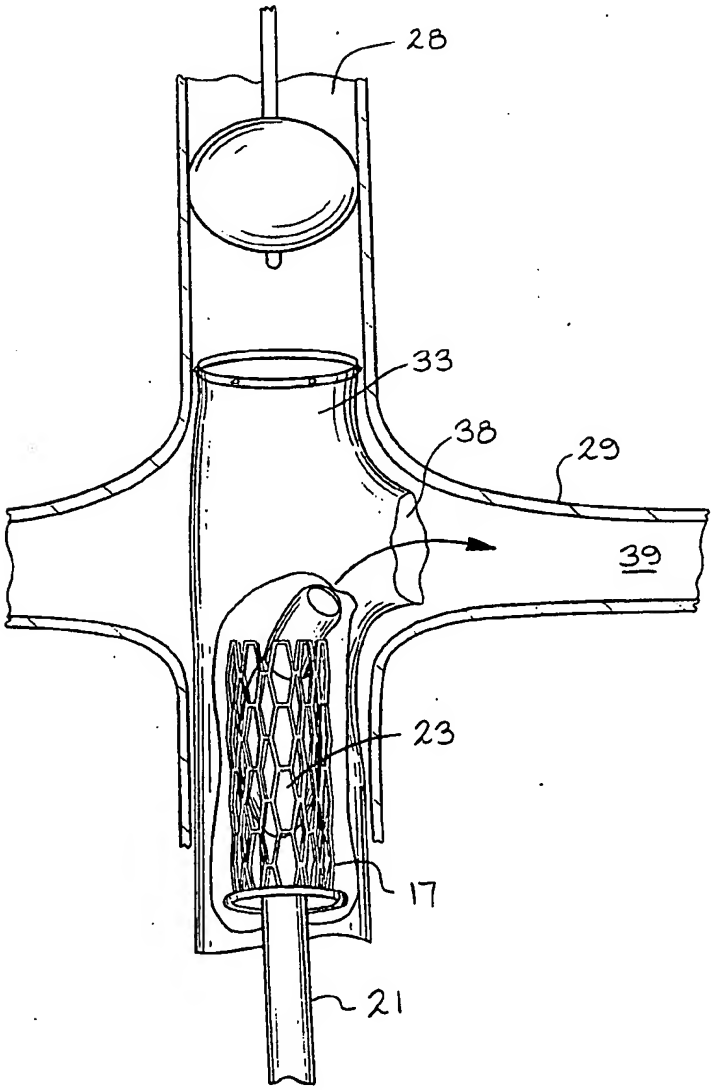
*Primary Examiner*—Glenn Dawson

*Attorney, Agent, or Firm*—Hodgson, Russ, Andrews, Woods & Goodyear

[57] **ABSTRACT**

A method of treating arterial disease at the intersection of two arteries using both a graft and stent. The graft is placed at the intersection of two arteries by the use of a balloon catheter. A device is used to make an opening in the graft at a point corresponding to the intersection of the two arteries. A stent is inserted into the graft and through the graft opening; the stent having an attachment mechanism to attach one end of the stent to the opening in the graft whereby the flow of blood at the intersection of the arteries is ensured.

**8 Claims, 11 Drawing Sheets**



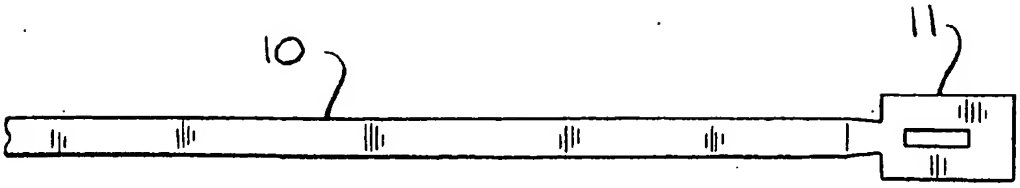



FIG. 1

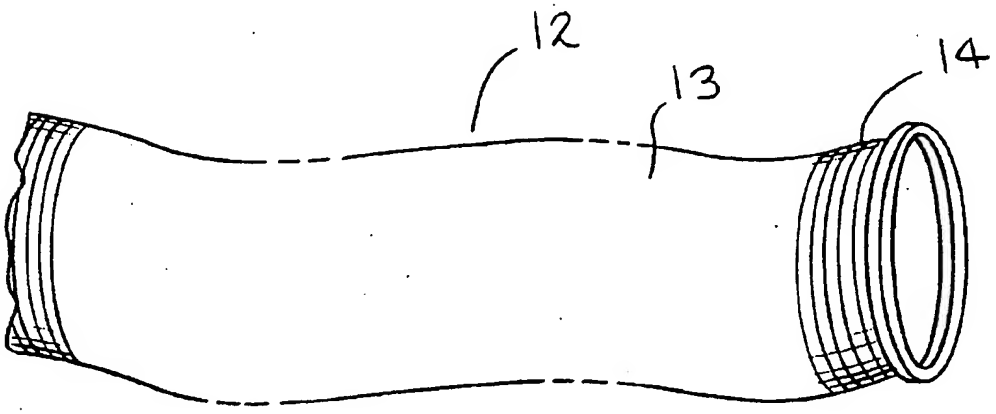



FIG. 2

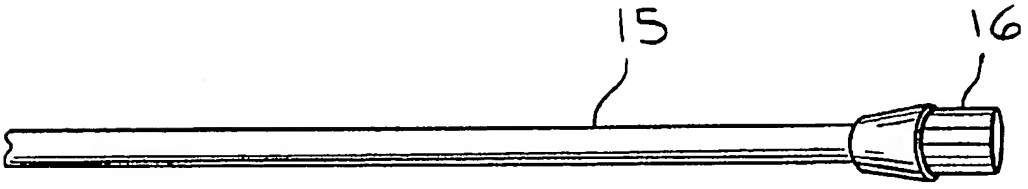



FIG. 3

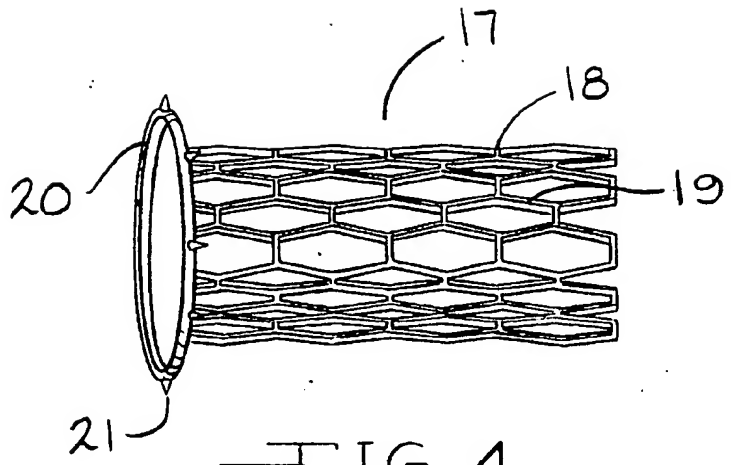



FIG. 4

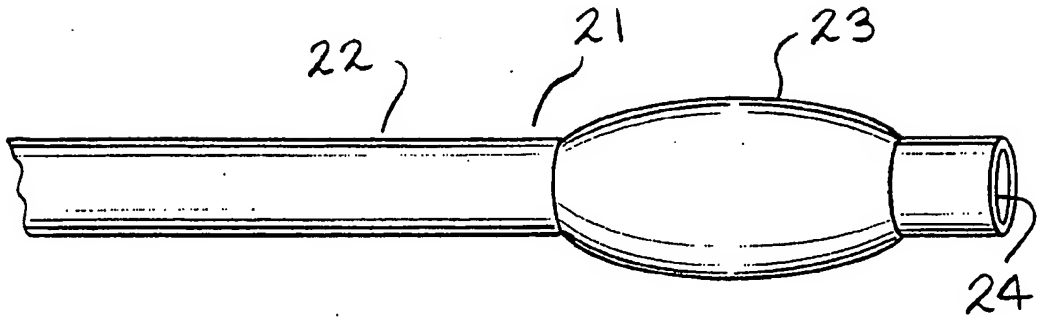



FIG. 5

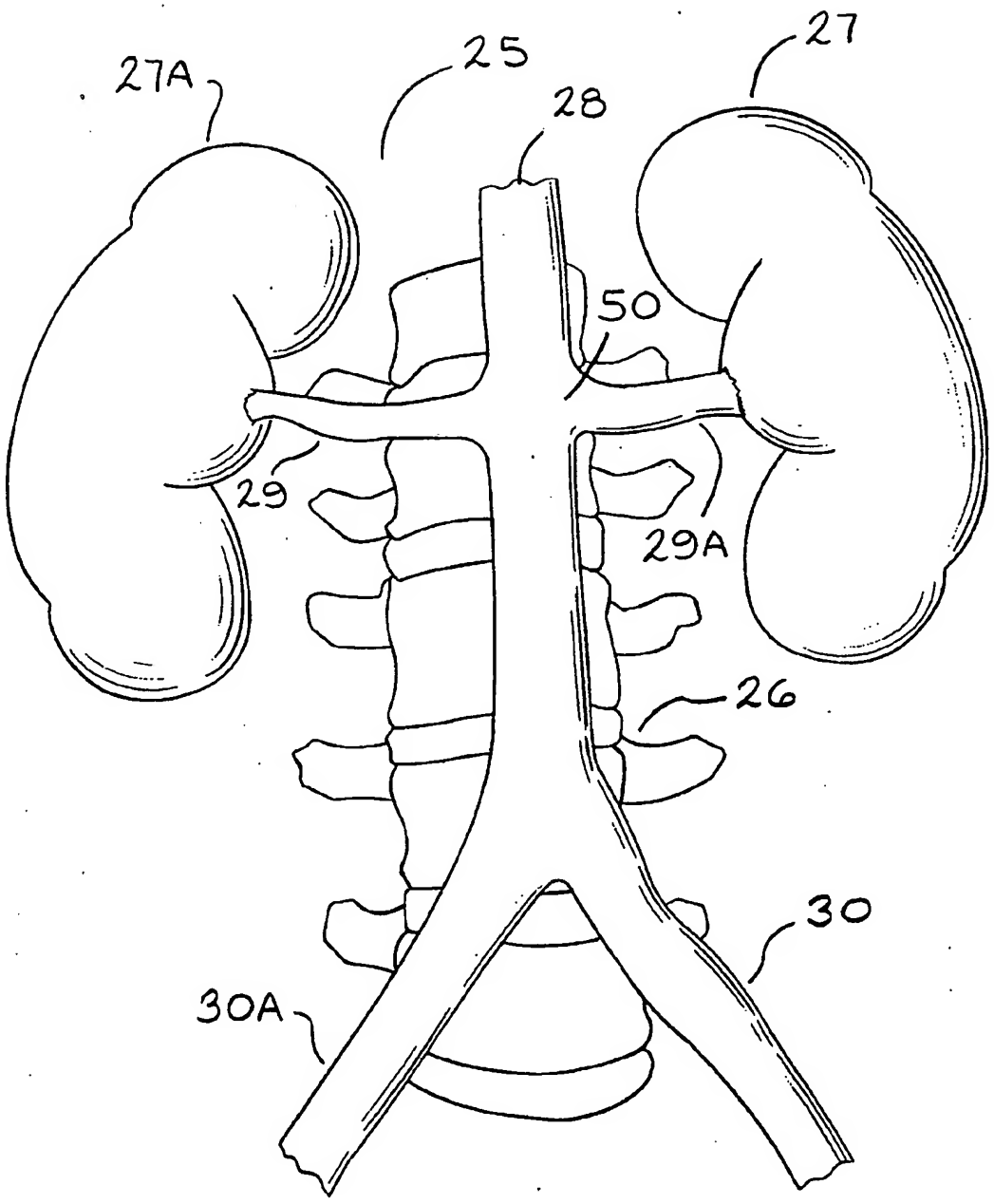



FIG. 6

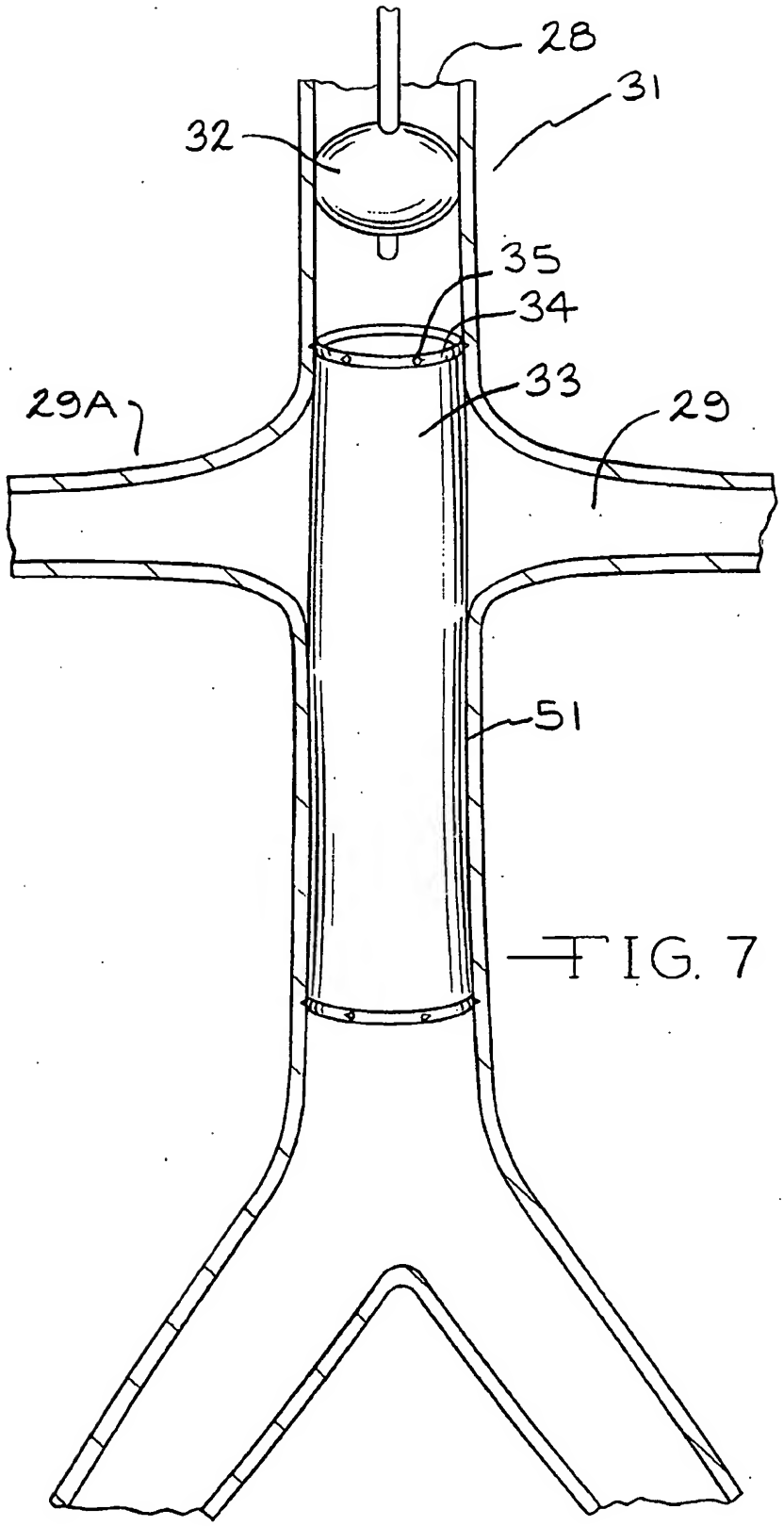



FIG. 7

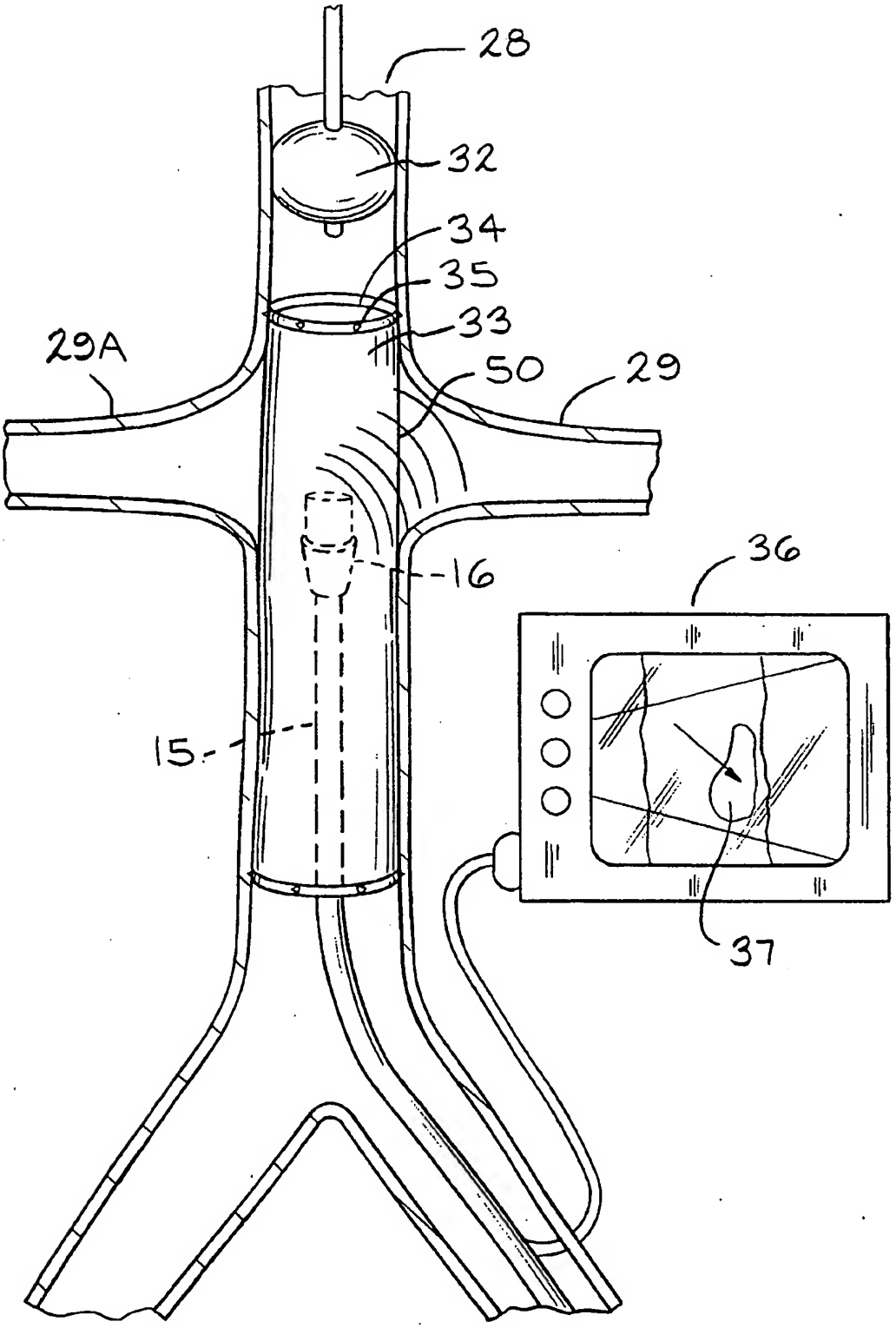



FIG. 8

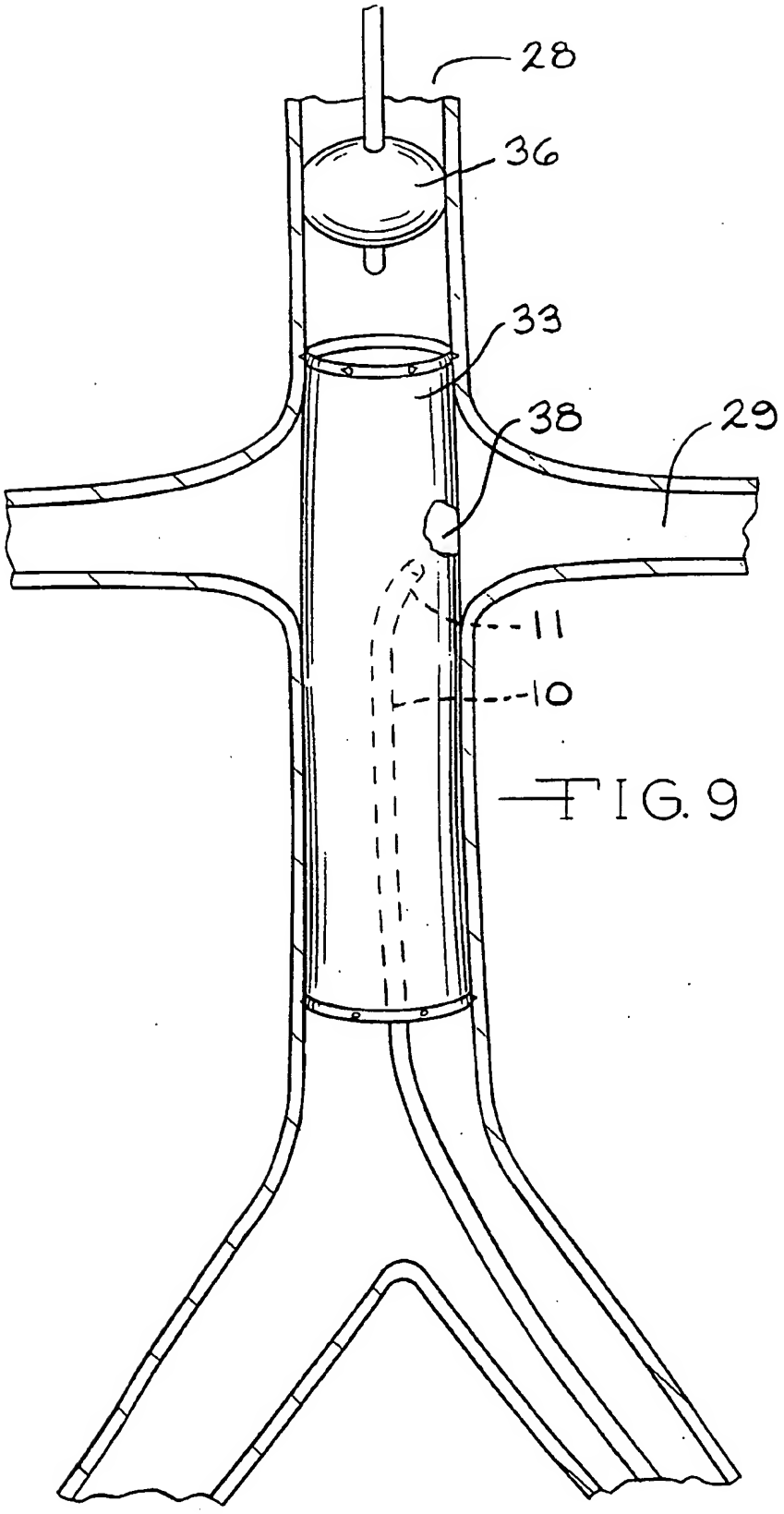



FIG. 9

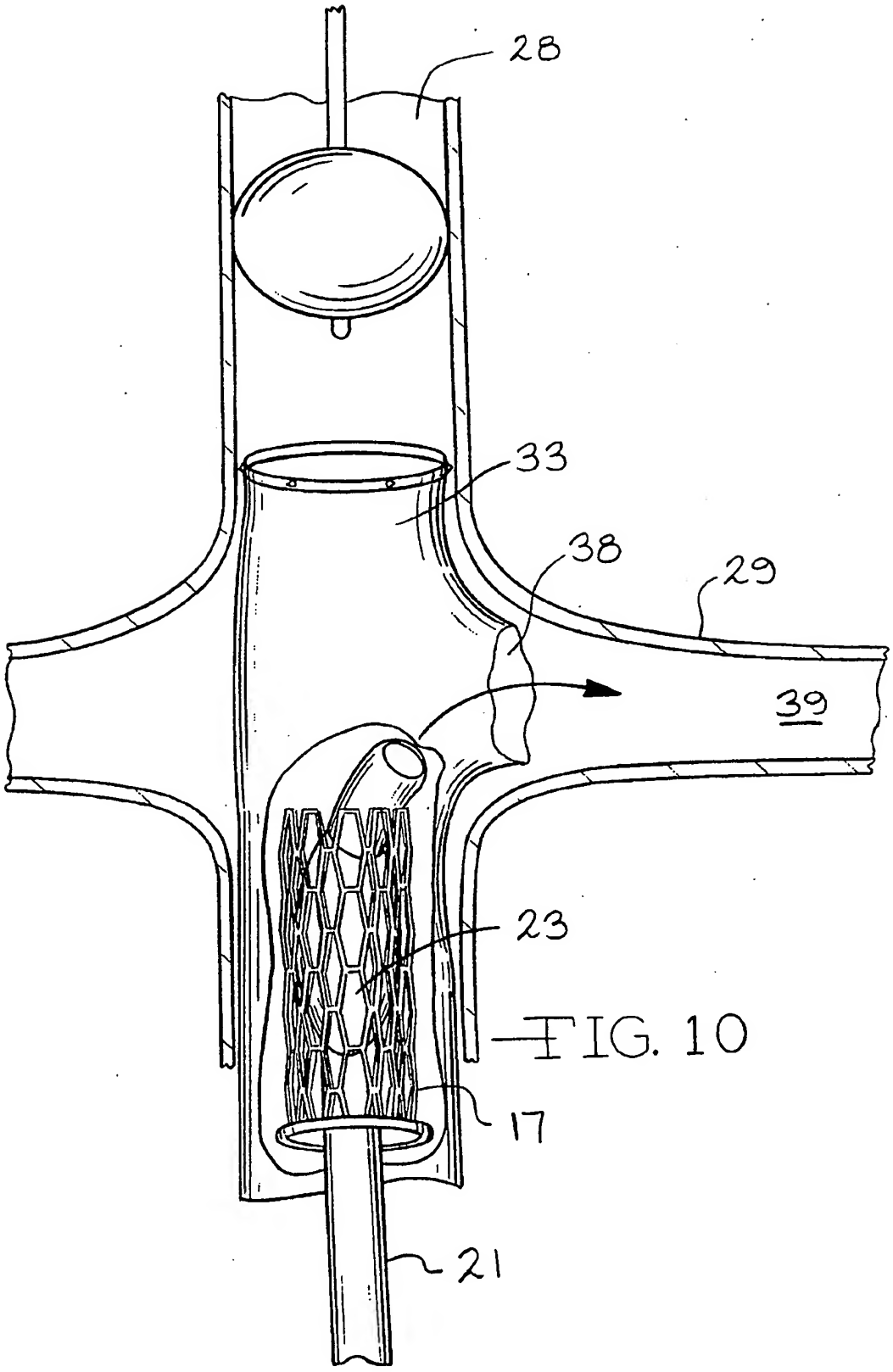



FIG. 10

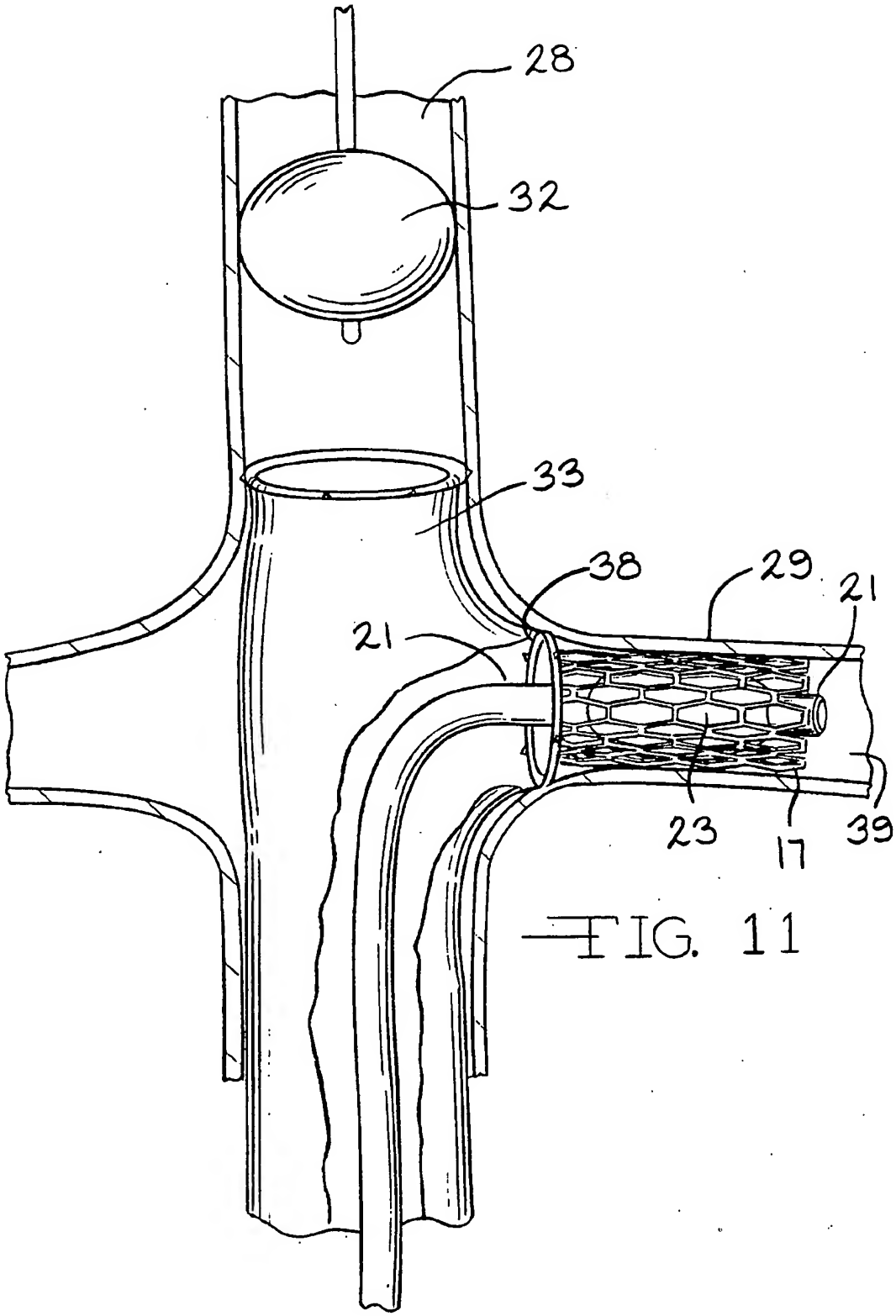



FIG. 11

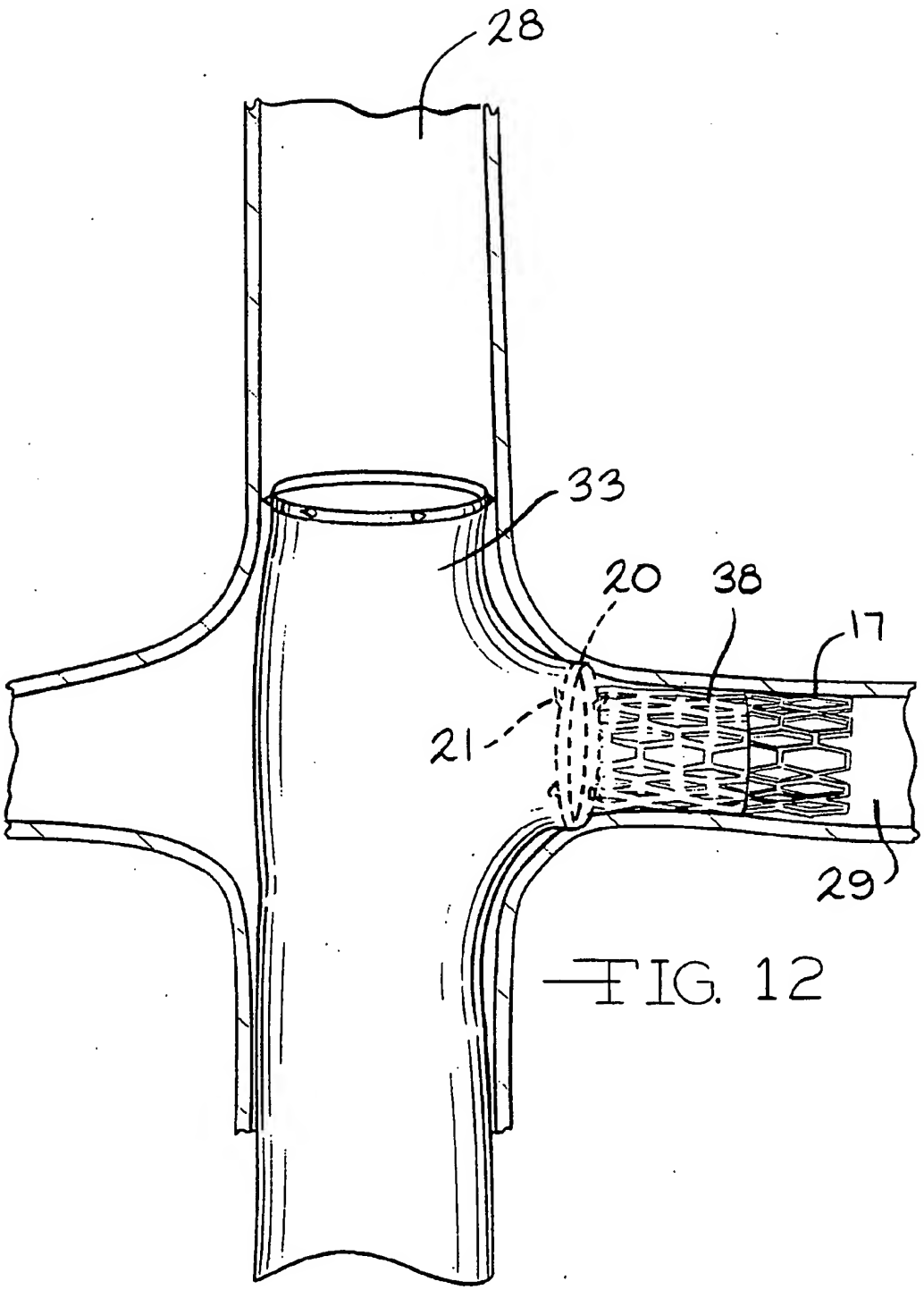



FIG. 12

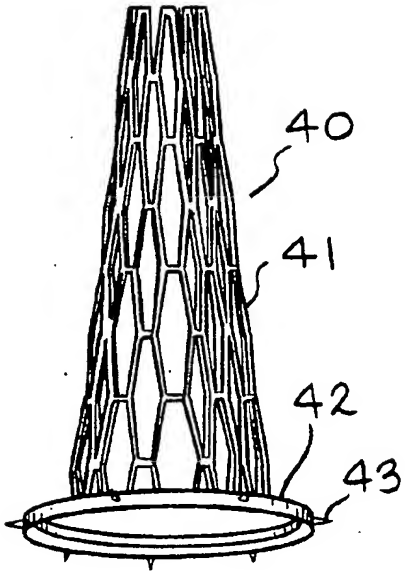



FIG. 13

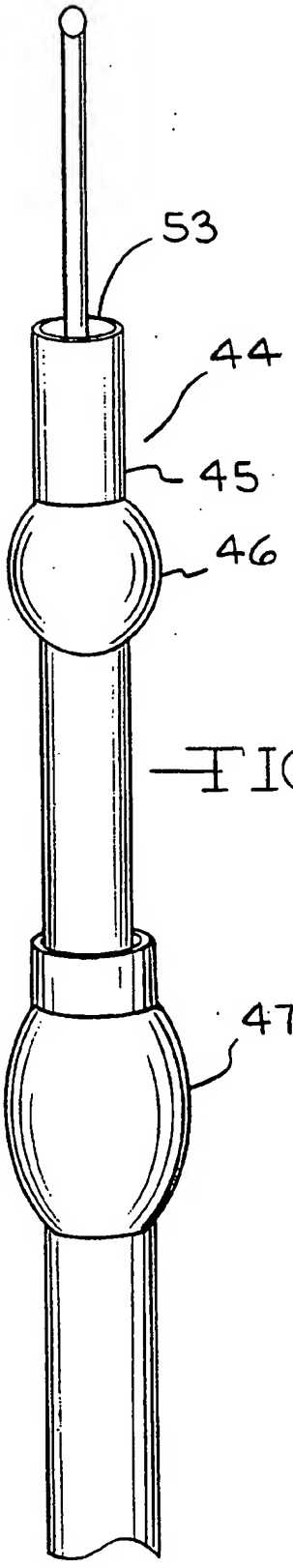



FIG. 14

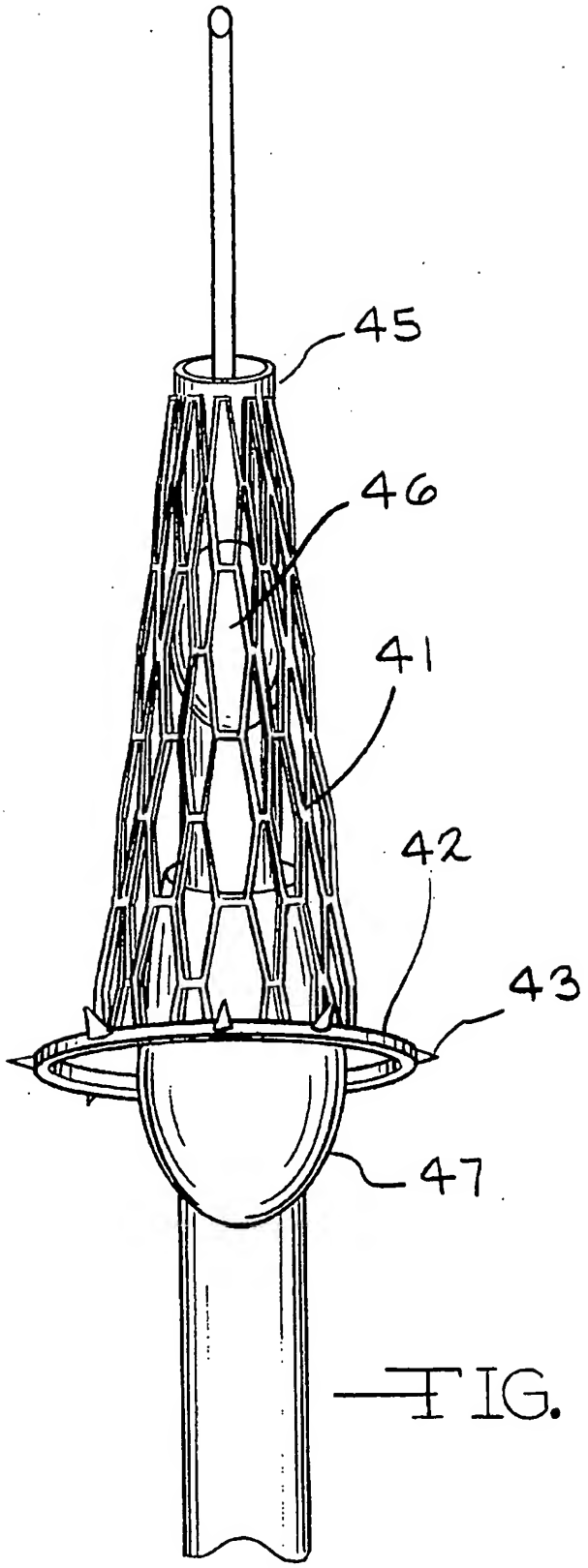



FIG. 15

# STENT AND METHOD FOR TREATMENT OF AORTIC OCCLUSIVE DISEASE

## BACKGROUND OF THE INVENTION

The present invention relates generally to the field of the treatment of aortic occlusive disease and in particular, to an improved stent and method for treating aortic occlusive disease in or around the intersection of the aorta and attendant arteries such as the renal arteries.

According to the prior art, aortic disease is often treated by surgical techniques involving the use of stents and grafts. For example, it is well known in the art to interpose within the stenotic portion of an artery a stent, whether made of stainless steel or other materials, capable of being balloon-expandable for strengthening the walls of a stenotic or occluded artery. Similarly, it is also well known in the prior art to use a graft to repair highly damaged portions of, for example, the aorta or other arteries thereby ensuring blood flow and reducing the risk of an aneurysm or rupture. The grafts, hollow tubes comprised of material such as dacron, are normally inserted within the walls of a damaged artery and can be sewn into position or expanded through the use of a stented balloon catheter.

A more severe problem occurs when it is necessary to use a graft at or around the intersection of a major artery (e.g., the aorta) with intersecting arteries (e.g., the renal arteries, carotid or brachiocephalic artery). While the graft is clearly required to strengthened and ensure the flow of blood through, for example, the aorta, the use of a graft effectively seals or blocks off the blood flow to the kidneys or cerebral circulation. Accordingly, it is often times impossible or impractical to use a graft to treat aortic disease at or around the intersection of the aorta and other arteries. Instead, a surgeon must attempt to repair the weakened walls of such artery using other surgical techniques having high failure rates and limited success.

The present invention solves the problem in the prior art by providing a graft and improved stent for use therewith and a method for treating aortic [occlusive] disease through the use of grafts at or around an intersection point.

## SUMMARY OF THE INVENTION

The present invention comprises a method and improved stent for use in the surgical treatment of aortic [occlusive] disease and in particular, to a method and improved stent for treating aortic occlusive disease at or around the intersection of various major arteries, e.g., the aorta and renal arteries, or brachiocephalic artery.

The improved stent comprises a strengthened mesh body portion having, at one end, a raised collar further including a series of protruding tines around the diameter thereof. The stent and collar are adapted to be inserted through a manufactured opening in a typical dacron or other graft by having the opening of the wall of the graft engage the collar and tines as the stent body portion extends therethrough. The stent is interposed through a graft at or around the point of intersection of a secondary artery (e.g., the point where the renal arteries and aorta intersect) thereby ensuring blood flow through the renal arteries into the aorta while ensuring the graft does not block such blood flow.

The method of the present invention includes interposition of a graft at or around the intersection of major arteries and thereafter, use of intravenous ultrasound or angiogram to visualize and measure the point on the graft where the arterial intersection occurs. A laser or cautery device is then interposed within the graft and is used to create an opening in the graft wall at the point of the intersection. The improved stent of the present invention is then, through the use of a double lumen balloon catheter interposed within the graft and through the created opening of the intersecting artery. A special collar having tines at one end of the stent is adapted to be secured tightly to the stent and to form a junction of the two arteries adapted to carry blood flow through the graft into the organ at issue. The balloon catheter is further adapted to expand the stent walls to ensure an appropriate positioning of the stent against the inner walls of the artery, while the other lumen of the catheter will supply continuous oxygenated blood into the organ while the procedure is undertaken.

The present invention also comprises an embodiment including a frusto-conical shaped stent approximating the diminishing diameter of some specific arteries, e.g., the renal arteries, to ensure an even better fit at the intersection and through the artery toward the kidneys.

Accordingly, one object of the present invention is to provide an improved stent and method for use in the treatment of aortic occlusive disease.

Still another object of the invention is to provide a method for using a well-known graft to repair an artery at or around a point of arterial intersection.

Yet another object of the invention is to provide an improved stent having particular characteristics and dimensions readily adaptable for use with the renal arteries or other arteries having varying diameters and to ensure the graft is secured to the arterial wall.

These and other objects of the invention will be apparent to one of ordinary skill in the art from the specification, the drawing figures and the following claims.

## DESCRIPTION OF THE DRAWING FIGURES

FIG. **1** is a view of a typical and well-known laser cautery device.

FIG. **2** is a view of a typical and well-known vascular graft.

FIG. **3** is a view of a typical and well-known intravenous ultrasound device.

FIG. **4** is a view of the improved stent of the present invention.

FIG. **5** is a view of a typical and well-known double lumen balloon catheter.

FIG. **6** is a view of the kidneys and aortic arteries interposed over the spinal column.

FIG. **7** is a view of the aorta and renal arteries having a graft interposed at the intersection thereof.

FIG. **8** is a view of the aorta and renal arteries demonstrating the use of intravenous ultrasound to detect and image the intersection point through the graft.

FIG. **9** is a view of the aorta and renal arteries with a laser or cautery and a created opening at the intersection of the aorta and renal arteries.

FIG. **10** is a view of the aorta and renal arteries and the use of a balloon cautery carrying the stent of the present invention toward the created opening.

FIG. **11** is a view of the aorta and renal arteries with the stent of the improved invention interposed through the graft.

FIG. **12** is a view of the aorta and renal arteries with the improved stent of the present invention fully interposed through the graft.

FIG. 13 is a view of another embodiment of the improved stent of the present invention.

FIG. 14 is a view of a double lumen and coaxial balloon catheter typical and well known in the art.

FIG. 15 is a view of a double balloon catheter carrying the improved stent of the present invention.

## DESCRIPTION OF THE PREFERRED EMBODIMENT OF THE INVENTION

The present invention comprises a method and an improved stent for use in the treatment of aortic disease and in particular, employing a graft to treat occlusive aortic disease as well as another aneurysm at and around the intersection of the aorta and other major arteries, such as the renal arteries to the kidneys or brachiocephalic artery and carotid artery to the brain.

The drawing figures illustrate the basic steps comprising the method, as well as illustrate the features of the improved stent.

FIG. 1 is a side elevation of a well-known laser cautery device, 10 having at one end, a cutting appendage 11. The laser cautery device 10 is adapted to be interposed within the walls of an artery and can be used to cut away tissue or, pursuant to the present method, create an opening in the wall of an arterial graft.

FIG. 2 is a side elevation of a well-known arterial graft 12 used in the treatment of occlusive disease. Graft 12 comprises a cylindrical body portion 13 made of, for example, dacron and end portion 14 comprising a flexible collar and re-enforcing means. Graft 12 is inserted and positioned through various techniques (e.g., balloon catheter) into an area of a diseased artery to reinforce the walls thereof and to prevent collapse or hemorrhaging.

FIG. 3 is a side elevation of a well-known intravenous ultrasound device 15 having at its one end, a sound emitting and visualizing head portion 16. The intravenous ultrasound device (IVUS) 15 is adapted to be inserted through an artery and to transmit signals to an appropriate receptor in the operatory so the operating surgeon may visualize through sound or other video images the extent and nature of the occlusive disease and also, the exact position where intersection of, for example, the aorta and renal arteries, occurs.

FIG. 4 is a side view of the improved stent 17 of the present invention. The stent comprises a cylindrical body portion 18 made from, in the preferred embodiment, a series of stainless steel "honeycomb" sections adapted to be flexible and extremely strong for supporting and ensuring the vitality of a diseased portion of an artery. Body portion 18 is adapted to be expanded in diameter through the use of a balloon catheter interposed therein to ensure a substantially tight fit against the walls of the artery. At one end of body portion 18 is a cylindrical collar 20 having a diameter in excess of that of the body portion. Collar 20 has evenly spaced around its diameter a series of protruding tines 21 adapted to grab or catch the walls of an artery or graft as is discussed more fully below. Stent 17 may be made of a host of other materials and have various different configurations, including a solid body portion 18. The various shapes and sizes of stents are well known in the prior art.

Adverting next to FIG. 5, a well-known double balloon catheter 21 is shown. The balloon catheter includes a hollow body portion 22 having an opening 24. The balloon catheter is adapted to be fed through the arteries and to carry visualizing instrumentation or other surgical devices within the arterial walls. A second lumen on the catheter perfuses the organ at issue (e.g., kidney). Expandable balloon 23 is interposed along body portion 22. Expandable balloon 23 may be controlled by the surgeon and may be expanded or contracted. Balloon catheter 23 is adapted to "carry" a stent into position and to be expanded for purposes of forcing a graft or stent against the walls of the artery. Deflation of the balloon allows the catheter to be removed while leaving the positioned stent or graft in place.

FIG. 6 is a view of the aorta and renal arteries, together with the kidneys. The system 25 comprises the aorta 28 extending behind the spinal column 26. Kidneys 27 and 28 are fed by branch renal arteries 29 and 29-A extending from the aorta. Ileac arteries 30 and 30-A are joined in the main portion of the aorta. The intersection between the aorta 28 and renal arteries 29 and 29-A denominated at point 50 is an area where the use of grafts or surgical techniques in the prior art to repair or remediate the aortic occlusive disease has been difficult and surgically risky. The present invention solves that problem.

Adverting next to FIG. 7, the present method includes the interposition of an arterial balloon catheter 32, with balloon expanded, into the top of the aorta 28. This stems blood flow and clears the way for the remainder of the surgery and method. Graft 33 is shown to be interposed through the intersection of aorta 28 and renal arteries 29 and 29-A. Graft 33 has at each end, a collar 34 having interposed around its diameter a series of tines 35. Graft 33 is interposed in position through the use of a balloon catheter, a technique well known in the prior art. The balloon catheter is deflated and the graft is left in place. Collar 34 and appended tines 35 serve to affix the graft in place by adhering to the walls of the artery at each end of the graft. Expansion of the graft through the use of the balloon catheter also ensures that the graft body portion 33 is snugly fit against the walls of the artery at, for example, 51.

Adverting next to FIG. 8, once graft 33 is in place, the surgeon feeds IVUS device 15 through the ileac artery into the aorta and within the graft walls. IVUS device 15 is connected electronically to a visualizing monitor or screen 36 in the operatory and, through the use of ultrasound, is able to visualize for the surgeon the point of intersection 50 between graft 33 and renal artery 29. The intersection point is visualized on monitor screen 36 at a point 37 which the surgeon is able to measure or "mark" using well-known, accurate techniques.

Adverting next to FIG. 9, after the point of intersection is "marked" at, for example, 37, the surgeon then inserts interarterially through the aorta and graft 33 a laser cautery device 10 having a cutting or burning device 11 at its end portion. Laser cautery device 10 is positioned by the surgeon at the visualized point of intersection between the graft 33 and renal artery 29 and an opening 38 is created through the graft at the point of intersection.

Once opening 38 is created, the surgeon is now in a position to strengthen the opening thereby allowing graft 33 to remain in place while ensuring blood flow through the renal arteries to the kidneys.

Adverting next to FIG. 10, graft 33 is shown to be positioned within aorta 28 at the intersection point between the aorta and renal artery 29. Opening 38 has been created through the use of laser cautery at the point of intersection in the wall of graft 33. Balloon catheter 21 has been interposed within the body portion of stent 17 and balloon 23 has been inflated to "carry" the stent into position. The balloon catheter and appended stent are fed by the surgeon

through the walls of the aorta and inserted graft **33** into a position for insertion through created opening **38**. Balloon catheter **21** may also contain at its end portion an appropriate visualizing aid for locating the opening. The surgeon, through positioning the catheter and appended stent, directs the catheter and stent through opening **38** in the direction of the kidney **39** through renal artery **29**.

Adverting next to FIG. **11**, stent **17** to be interposed down through the opening created in graft **33**. Tines **21** are shown to be interposed within the graft surface to hold the stent in place. Balloon **23** of catheter **21** is then inflated to ensure firm engagement of stent **17** against the walls of artery **29**. Balloon **23** can then be deflated and the balloon catheter removed from the graft and arteries.

Adverting next to FIG. **12**, stent **17** is shown to be positioned through graft **33** and down the length of artery **29** toward the kidneys. Opening **38** has now been extended across the surface of the stent **17** and collar and appended tines **20** and **21** firmly engage opening **38** created in graft **33**. Accordingly, blood flow through the aorta **28** and renal arteries **29** is ensured and, as well, any occluded area around the intersection of the aorta and renal artery is effectively repaired and strengthened.

Adverting next to FIG. **13**, a second embodiment of a stent **40** is disclosed. Stent **40** includes a frusto-conical body portion **41** comprised of a mesh surface for strength. Body portion **41**, as indicated, has a length of decreasing diameter and, at its larger end, has interposed around the diameter a collar **42** having a series of evenly spaced tines **43** as in prior embodiments. The frusto-conical shape of stent **40** is particularly adapted for interposition through the aorta and down the length of renal artery **29**, **29**-A or any other artery of decreasing diameter.

Further, stent **40** is adapted to be "carried" to the insertion point by a double lumen balloon catheter illustrated in FIG. **14**. Double catheter **44** comprises a body portion **45** having an opening **53** through the length thereof and includes a first balloon **46** and a second balloon **47**. The balloons, well known in the prior art, are inflatable and deflatable by the surgeon. Balloon **46** is generally smaller in size than balloon **47** and accordingly, as is illustrated in FIG. **15**, stent **40** is interposed over double balloon catheter **44** in a manner such that the smaller balloon **46** resides in the area of stent **40** having the smallest diameter, while larger balloon **47** is positioned at the end of the stent including the collar portion and larger diameter. The double catheter is inserted in the identical manner previously described in, for example, FIG. **10**, and, once in position, balloons **46** and **47** are inflated and deflated and otherwise manipulated to ensure collar portion **42** and tines **43** engage the opening. As well, stent body portion **41** is thereby snugly engaged against the walls of the decreasing diameter of the renal artery. Accordingly, the dimensional characteristics of improved stent **40** make it directly applicable to arteries of decreasing diameter such as the renal artery and further serves to ensure the best and snuggest fit possible while maintaining blood flow through the artery and attendant aorta at the point of intersection.

Accordingly, the present invention describes an improved stent and method for insertion thereof that can be readily adapted and used for the surgical treatment of aortic occlusive disease in or around the point of intersection of the aorta and other arteries through the use of a well-known graft and improved stent.

Many modifications to the invention would be apparent to one of skill in the art. For example, stent configurations and grafts of various dimensions, materials and size could easily be adapted for use with the invention. Moreover, use of the collar configuration and tines is readily adaptable to use with grafts only or stents and the surgeon may chose to use the stent alone or graft in various other parts of the arterial system whether involving intersections of arteries or not.

Positioning of the graft and stents is shown to be accomplished through the use of a balloon catheter. Other methods of positioning the stent would equally be applicable without varying from the scope and purpose of the invention. These and other modifications to the invention fall well within the scope of the following claims and will be apparent to one of skill in the art.

I claim:

**1**. A method for treating arterial disease at an intersection of two arteries, using a graft and stent, comprising the steps of:

providing a graft adapted to be inserted into an artery to be treated;

inserting said graft using a balloon catheter in positioning said graft to a point of intersection of two arteries to be treated;

identifying a point within said graft located at the intersection of the arteries to be treated;

manufacturing an opening in said graft at the point of said intersection of said arteries to be treated;

inserting a stent through said opening thereby creating a pathway between said arteries to be treated;

affixing said stent to said graft at the opening;

whereby the cooperation of the graft and stent inserted through the opening ensures the flow of blood at the intersection of the arteries to be treated.

**2**. The method according to claim **1** wherein said identifying step is accomplished using an intravenous ultrasound system.

**3**. The method according to claim **1** wherein the manufacturing step comprises using an electrocautery laser device.

**4**. The method according to claim **1** wherein said affixing step comprises the use of a plurality of tines interposed around the diameter of said stent.

**5**. The method according to claim **1** wherein said stent is adapted to be expanded within the walls of said artery.

**6**. The method according to claim **1** wherein said affixing step comprises the use of a collar having a plurality of tines interposed on the diameter of said stent.

**7**. The method according to claim **1** wherein said stent is frusto-conical in shape.

**8**. The method according to claim **1** wherein said stent is cylindrical in shape.

* * * * *

US005609627A

# United States Patent [19]

Goicoechea et al.

[11] Patent Number: 5,609,627

[45] Date of Patent: Mar. 11, 1997

[54] METHOD FOR DELIVERING A BIFURCATED ENDOLUMINAL PROSTHESIS

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[73] Assignee: Boston Scientific Technology, Inc., Maple Grove, Minn.

[21] Appl. No.: 317,763

[22] Filed: Oct. 4, 1994

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 312,881, Sep. 27, 1994.

[30] Foreign Application Priority Data

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Jun. 10, 1994 [EP] European Pat. Off. ..... 94401306

[51] Int. Cl.[6] ..... A61F 2/06

[52] U.S. Cl. ..... 623/1; 606/108; 606/194

[58] Field of Search ..... 623/1, 12; 606/108, 606/191, 194; 604/96

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*Primary Examiner*—Michael J. Milano
*Attorney, Agent, or Firm*—Ratner & Prestia

[57] ABSTRACT

The invention comprises:

An introducer for delivering into the vasculature a straight or bifurcated stent or prosthesis; a method for delivering into the vasculature a straight or bifurcated stent or prosthesis; a method of treating and angeological disease using a bifurcated stent; an endoluminal stent having perpendicular hoop members, each hoop member formed of wire in a sinuous configuration, at least some of juxtaposed apices in neighboring hoops being secured to one another, such stents also forming axially aligned segments in straight stents, and segments of bifurcated stents in particular embodiments. Certain embodiments of such stents also include barbs, fabric covering and radiopaque markers.

2 Claims, 23 Drawing Sheets

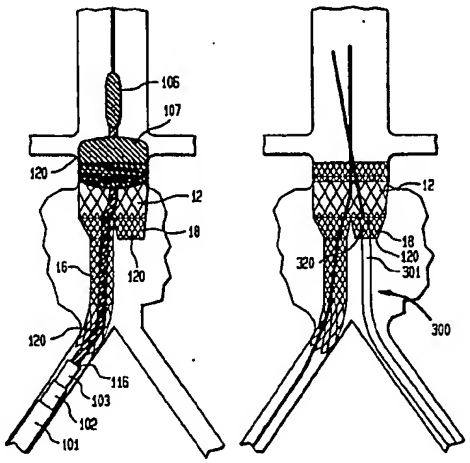

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FIG. 1A

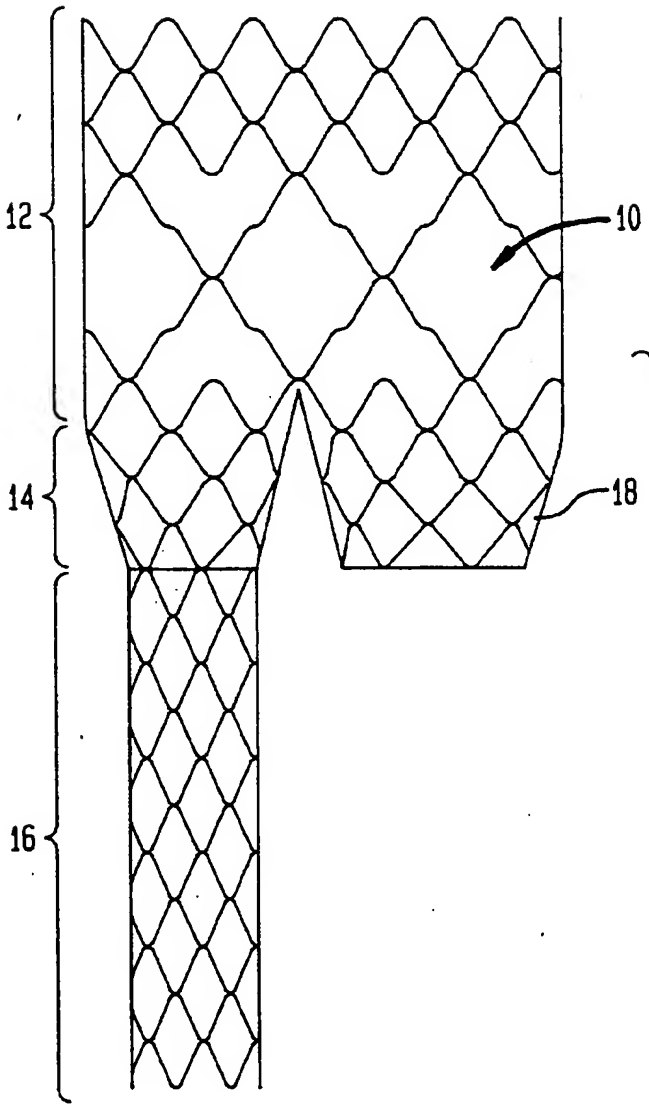



FIG. 1B

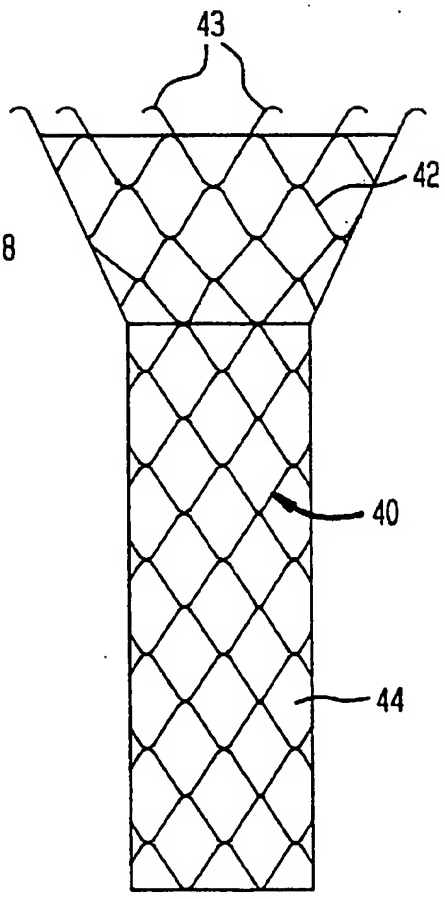


FIG. 2A

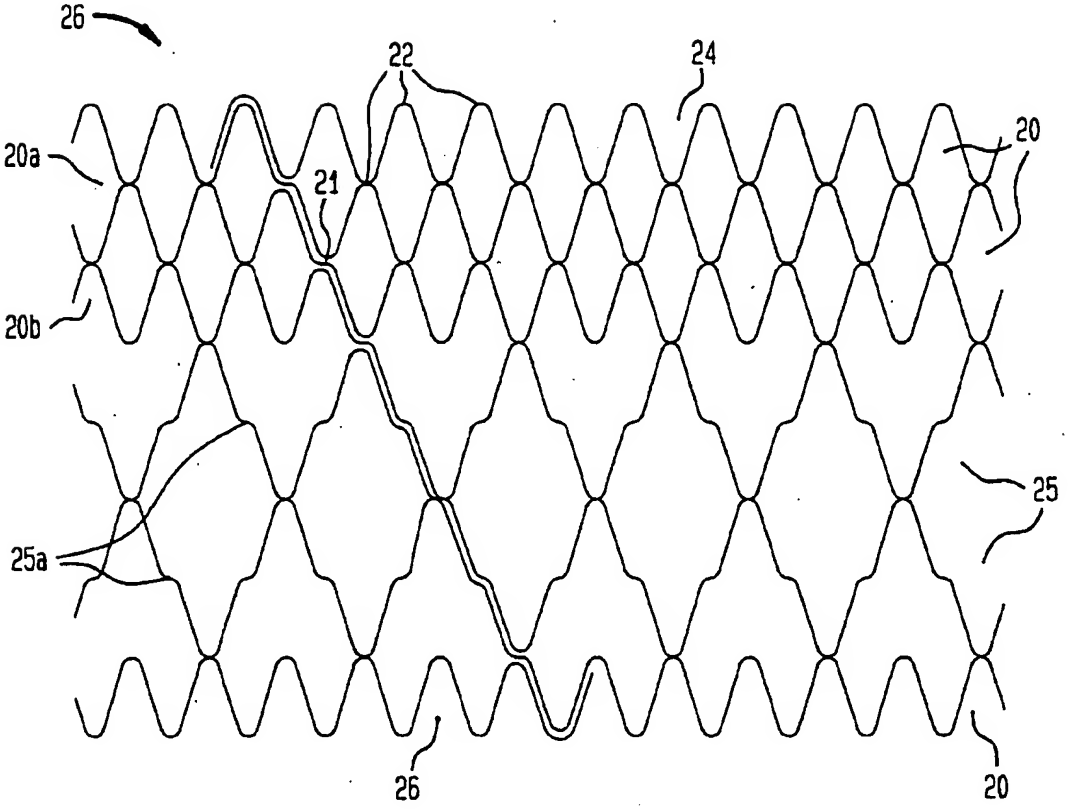



FIG. 2B

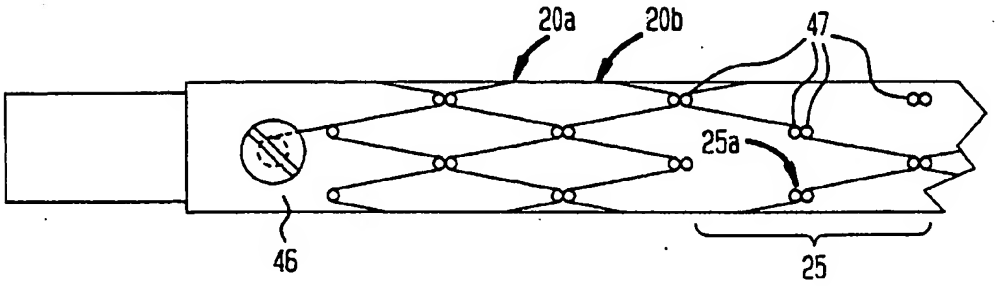


FIG. 3

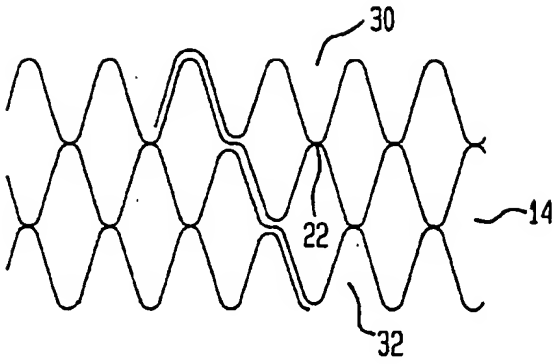



FIG. 4A

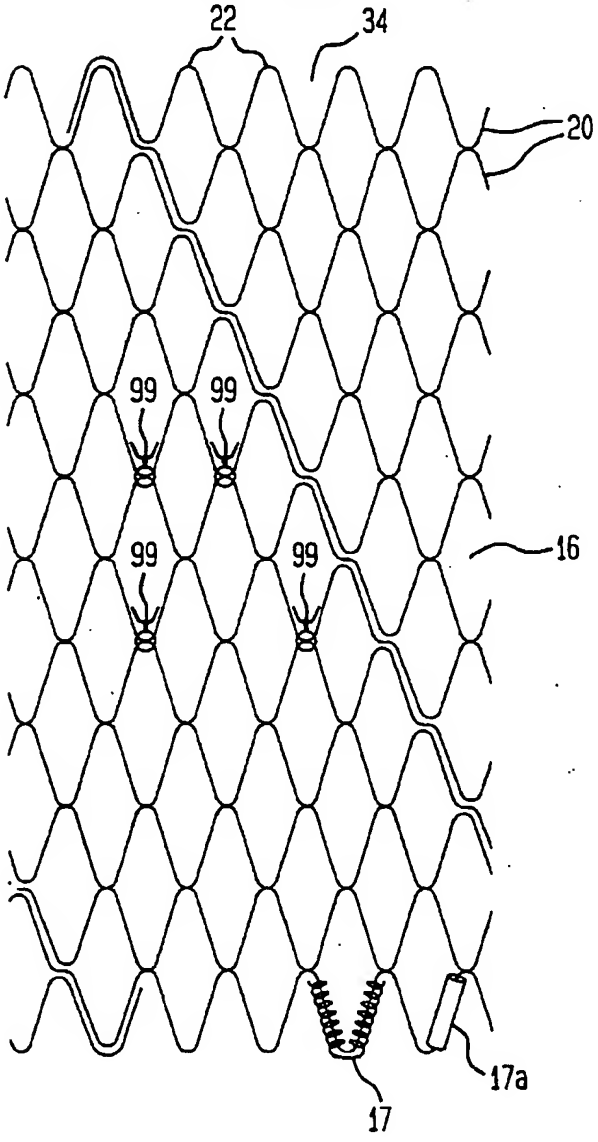


FIG. 4F

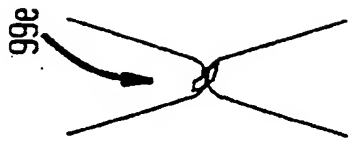



FIG. 4E

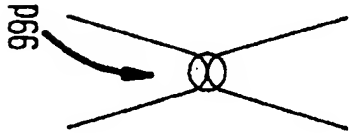



FIG. 4D

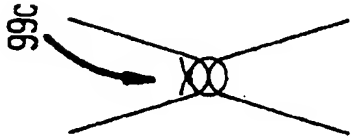



FIG. 4C

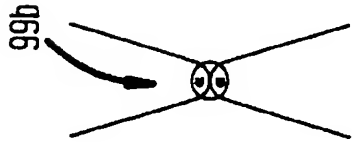



FIG. 4B

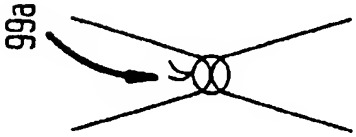


FIG. 5

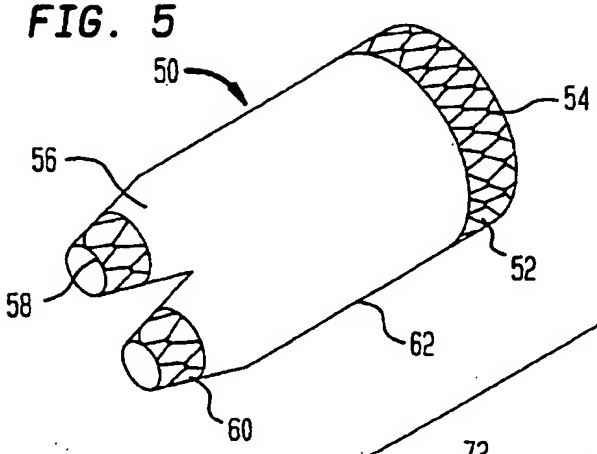



FIG. 6

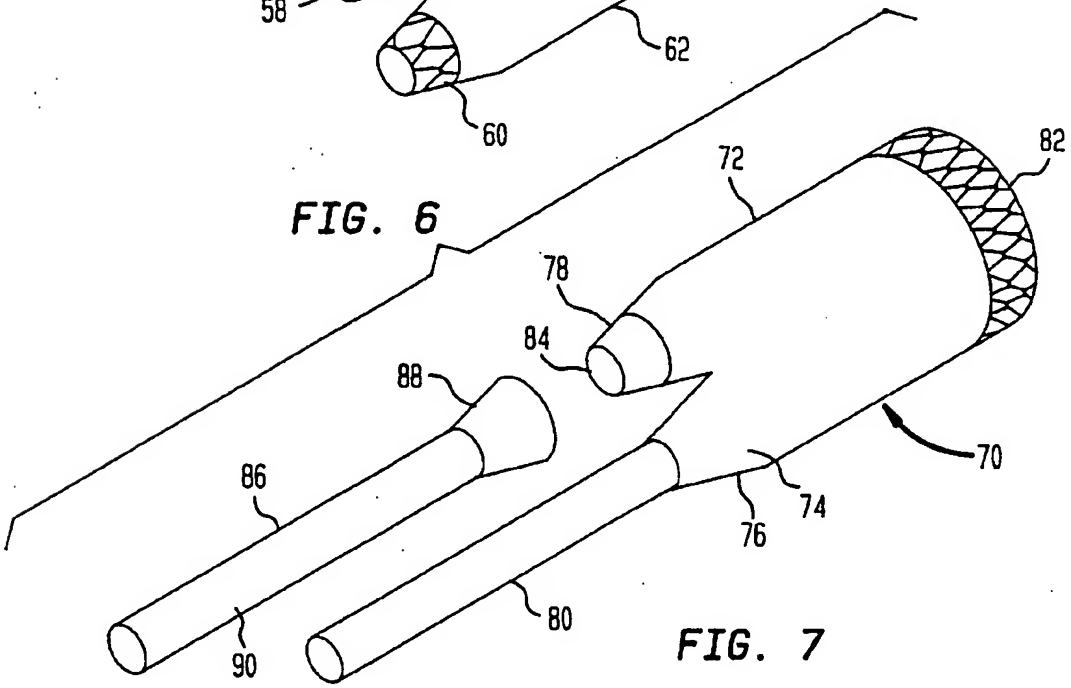
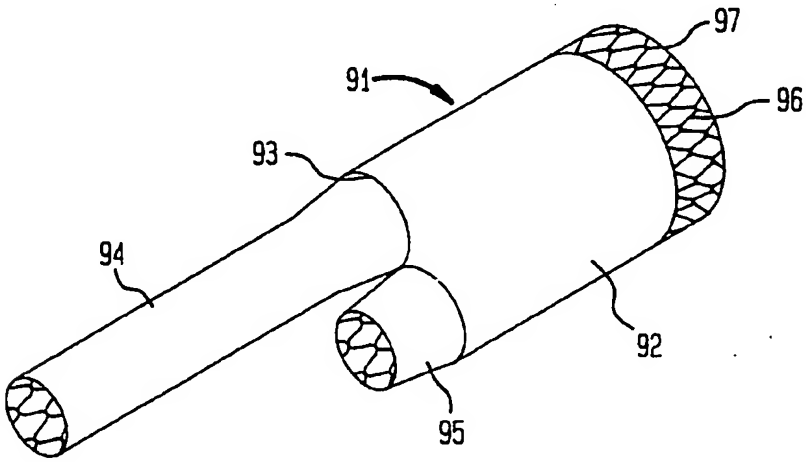



FIG. 7



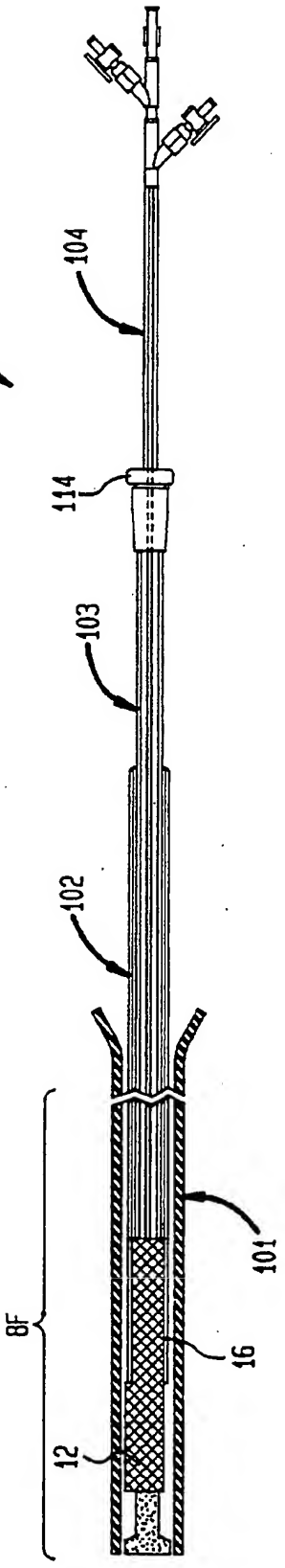



FIG. 8A

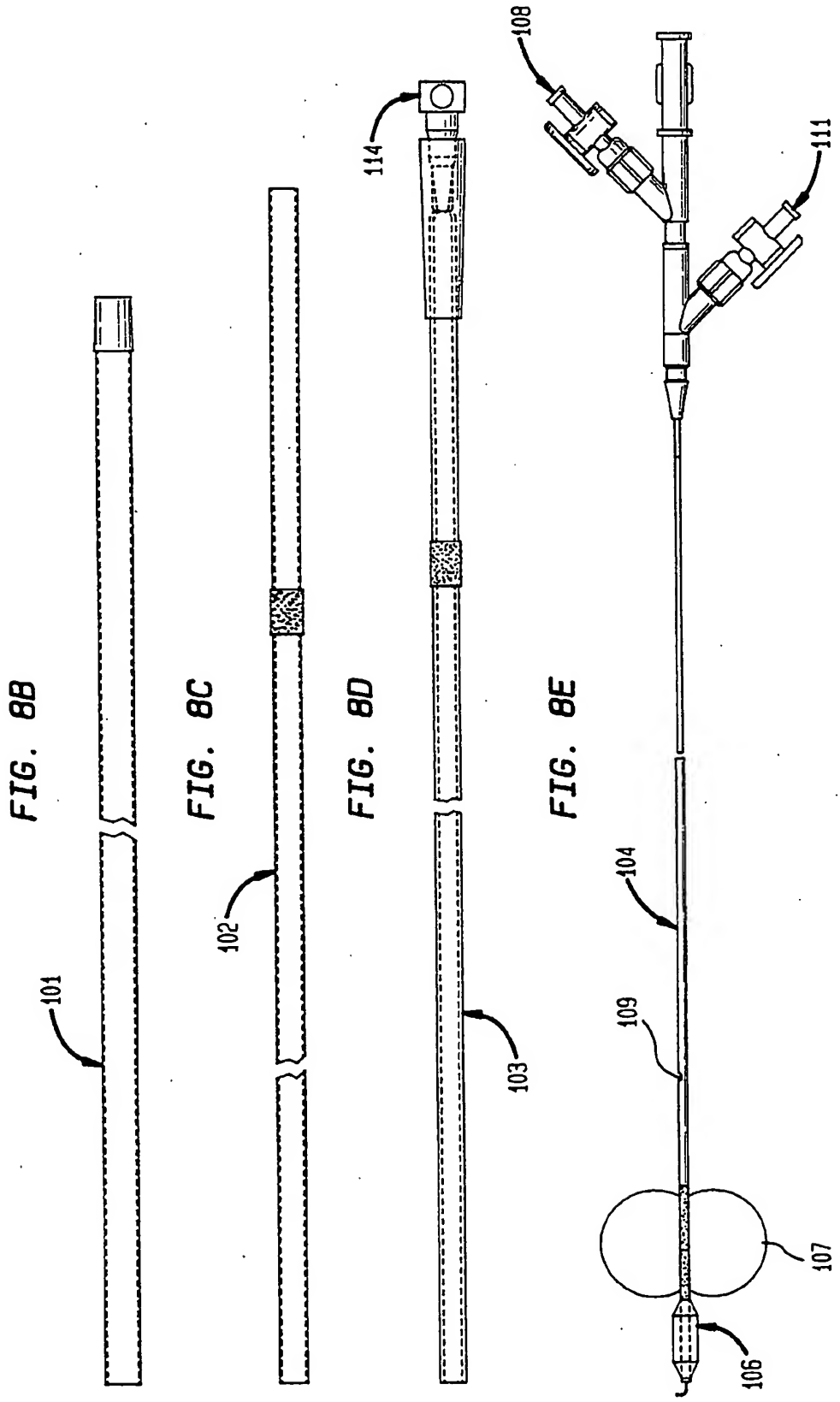


FIG. 8B
101
FIG. 8C
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FIG. 8D
114
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FIG. 8E
108
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104
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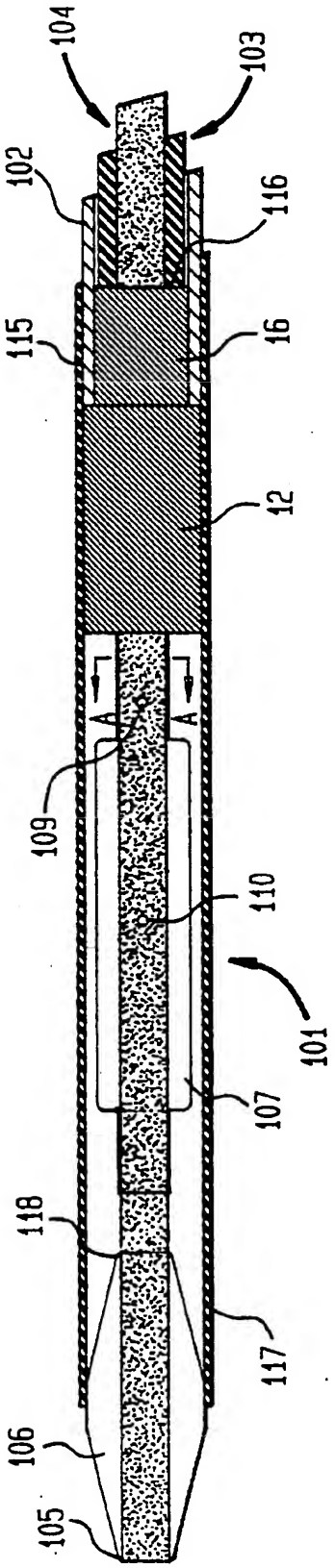
107
106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A
A
100
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110
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117
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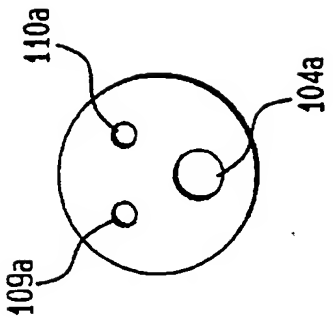
105

FIG. 8F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104a
109a

FIG. 8G

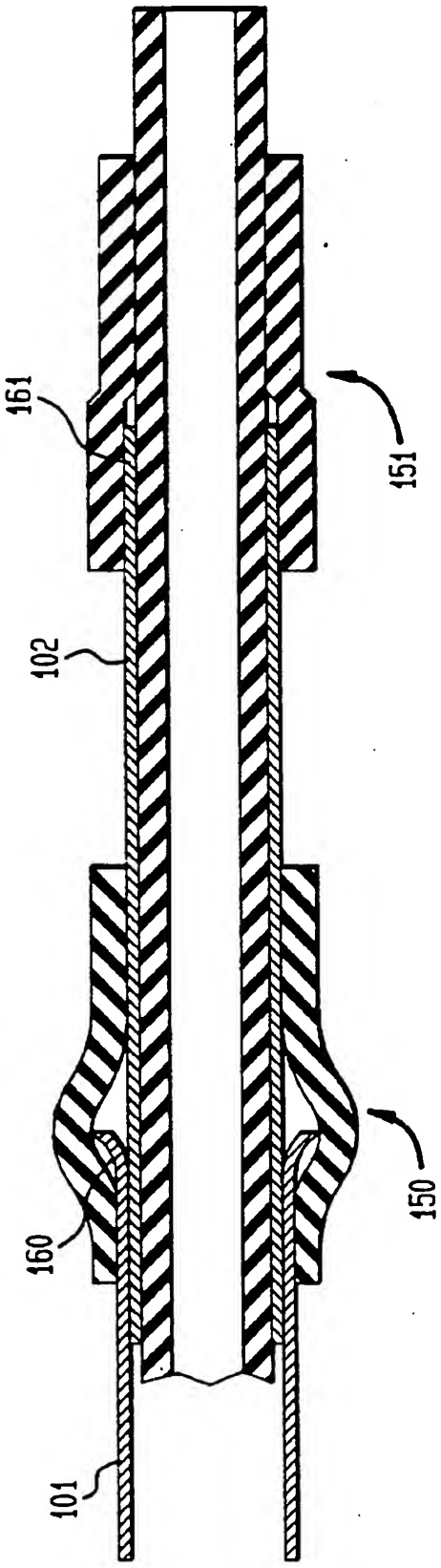


FIG. 9

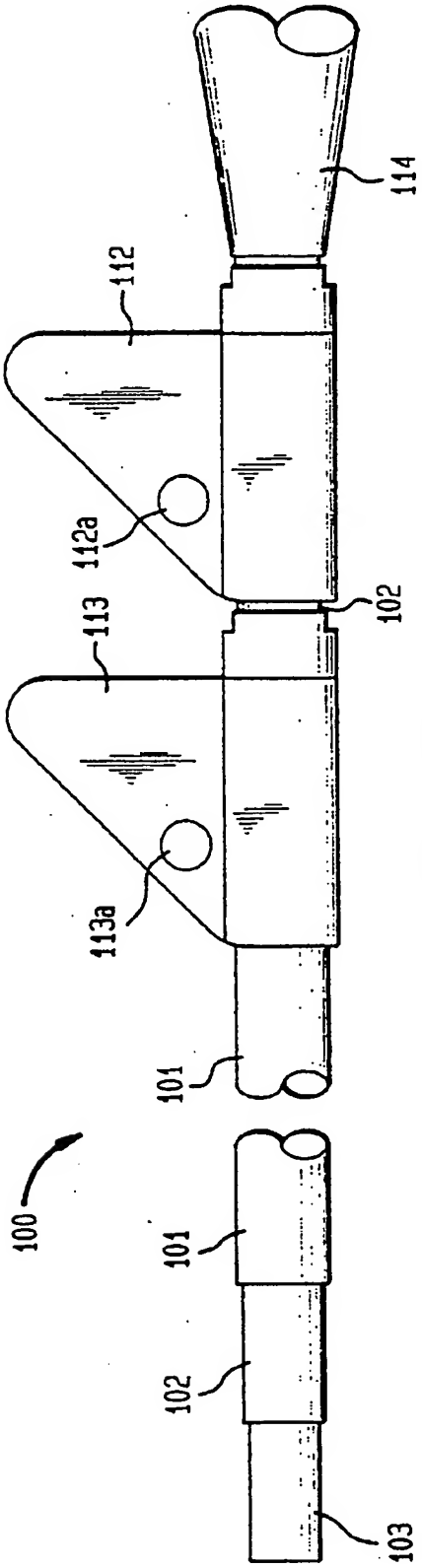


FIG. 10A

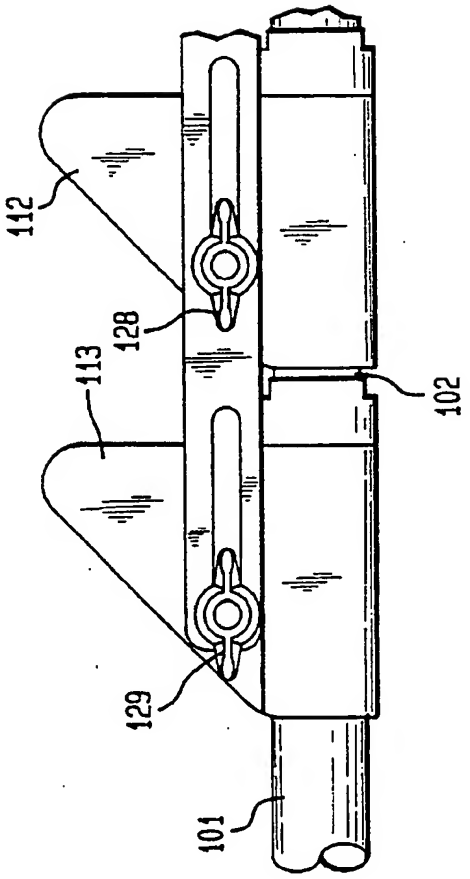


FIG. 10B

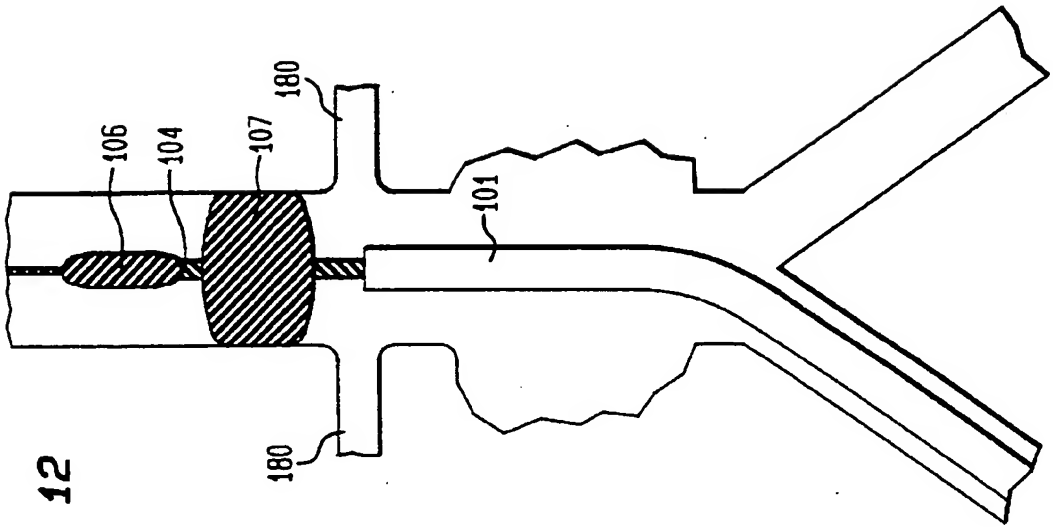


FIG. 12

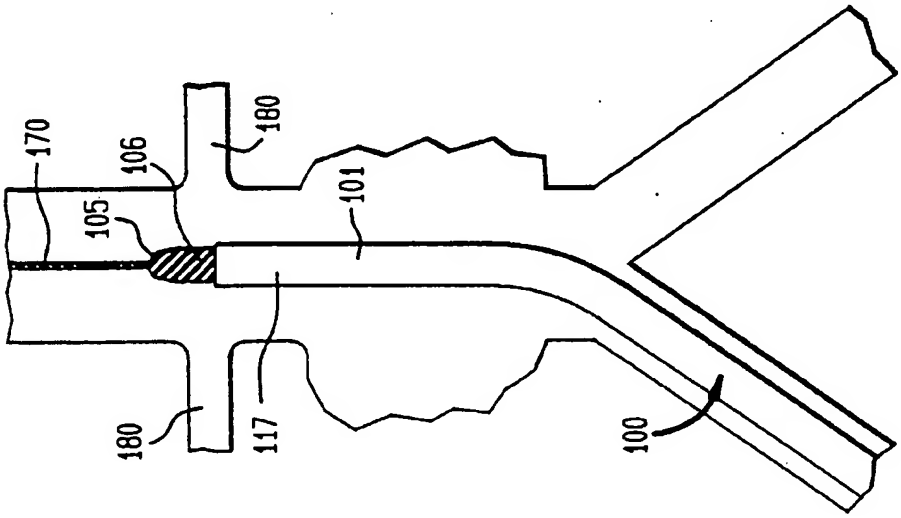


FIG. 11

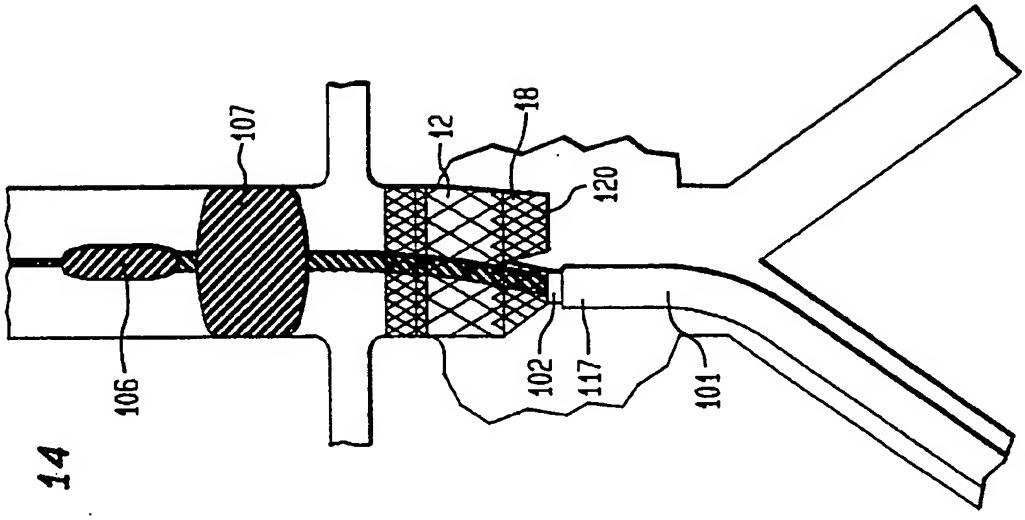


FIG. 14

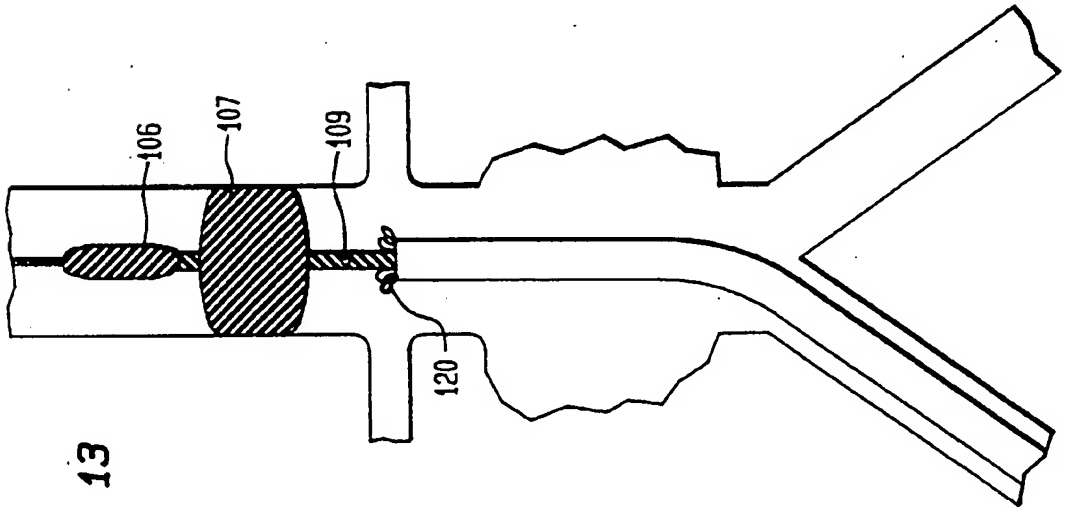


FIG. 13

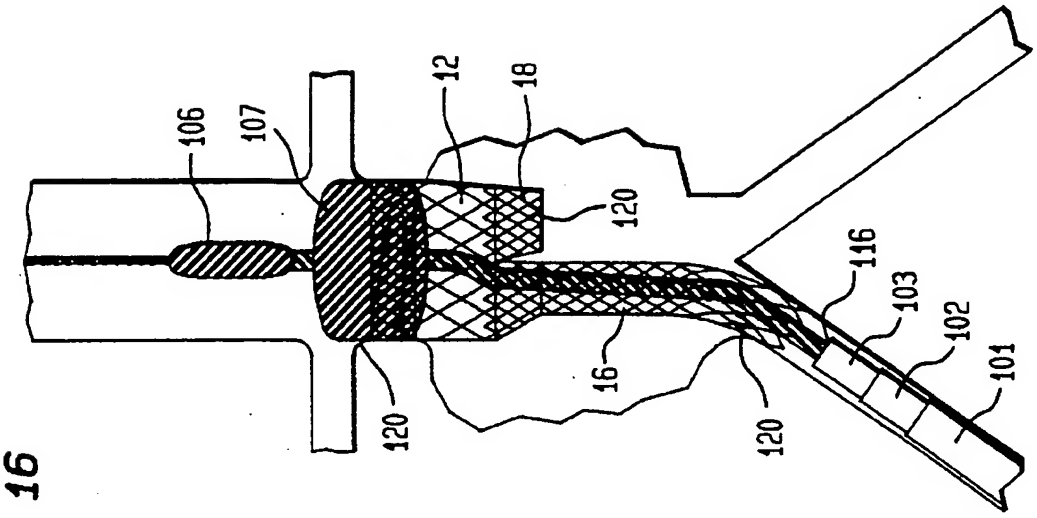
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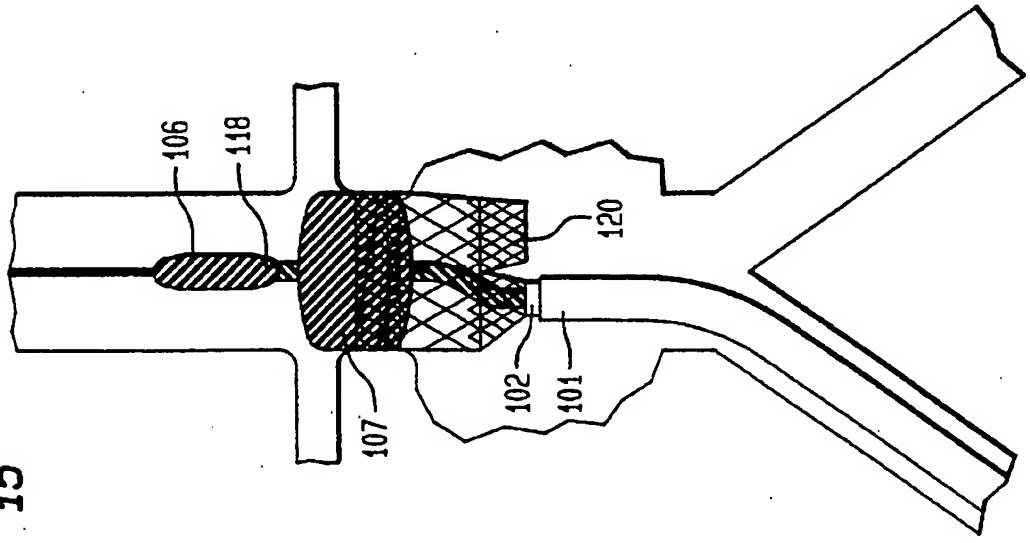
FIG. 16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101
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FIG. 15

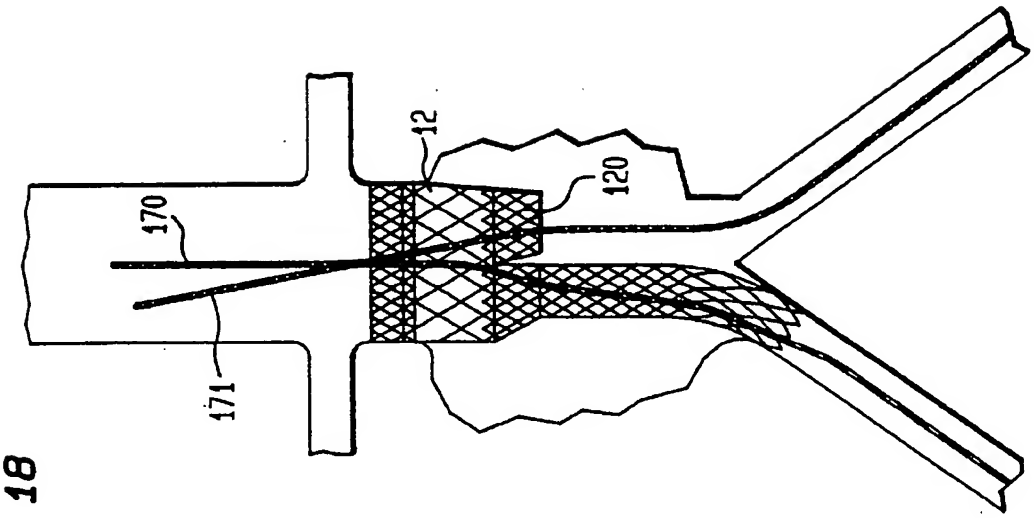



FIG. 18

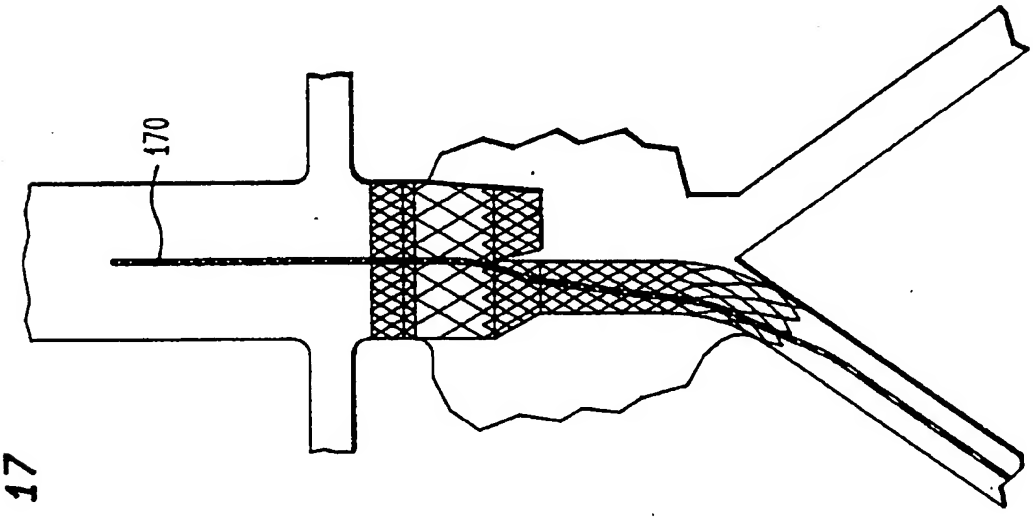



FIG. 17

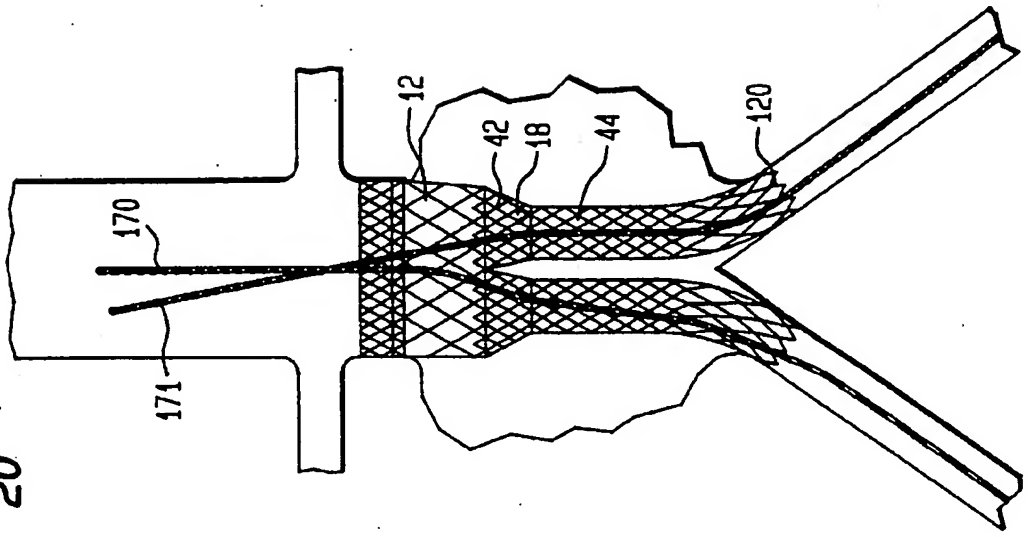



FIG. 20

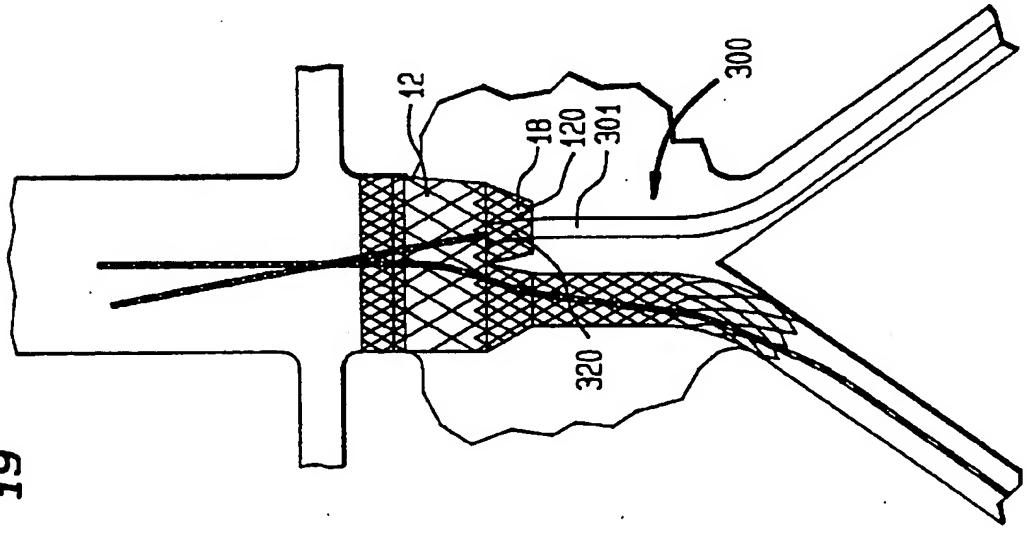



FIG. 19

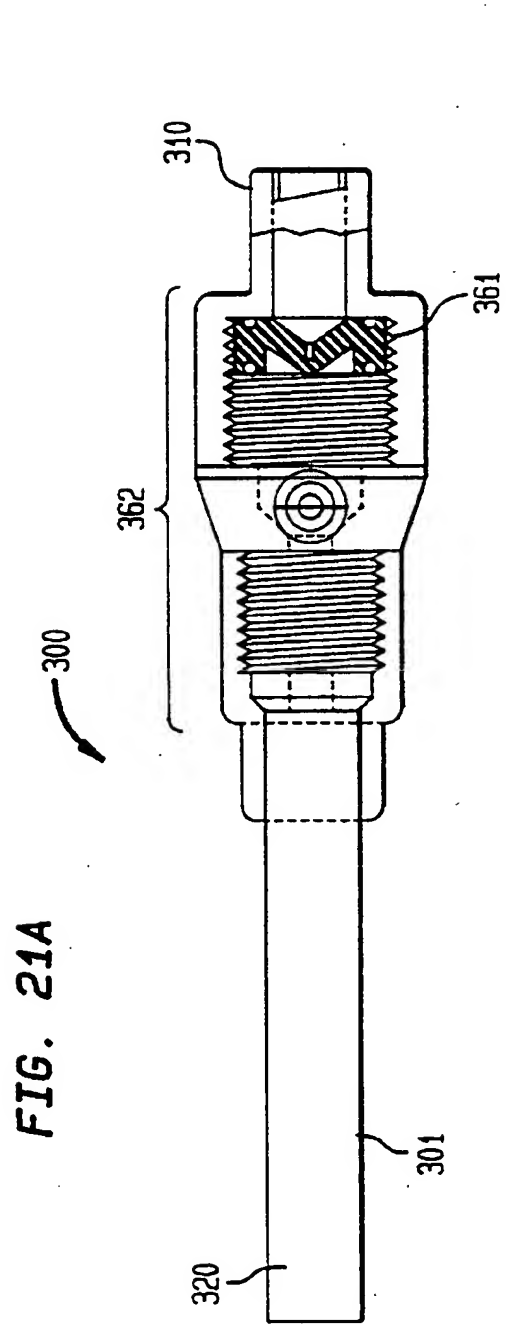



FIG. 21A

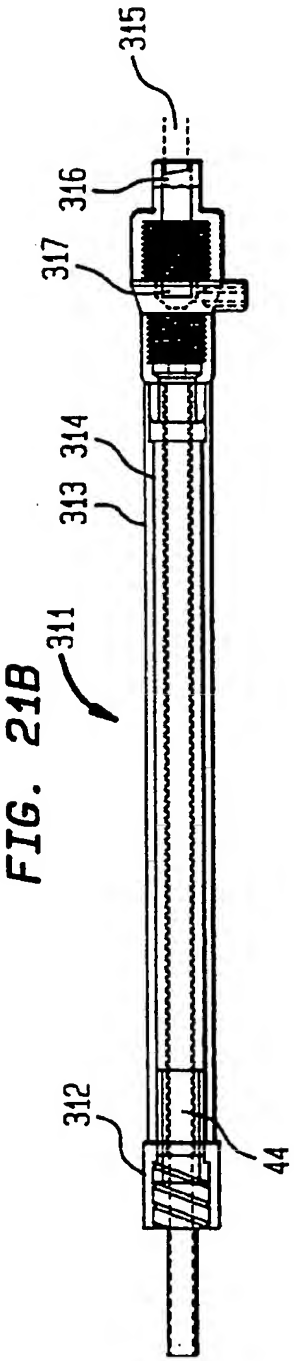



FIG. 21B

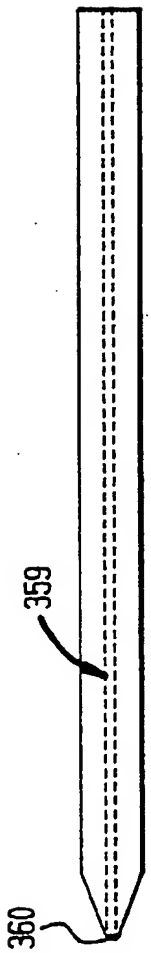



FIG. 21C

FIG. 23

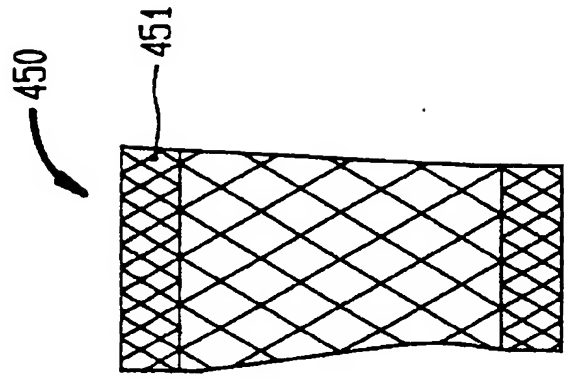
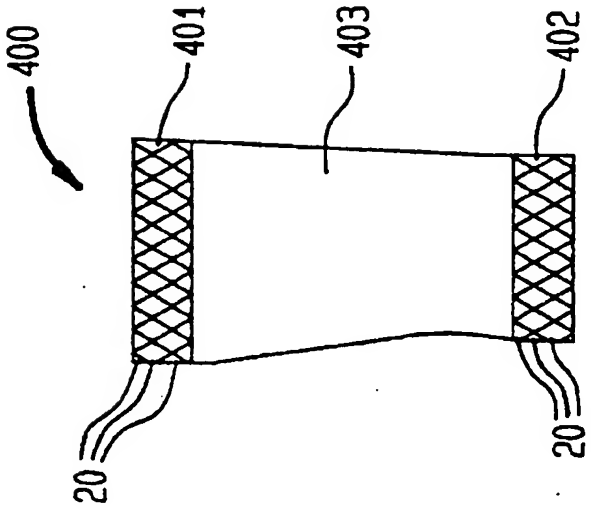



FIG. 22



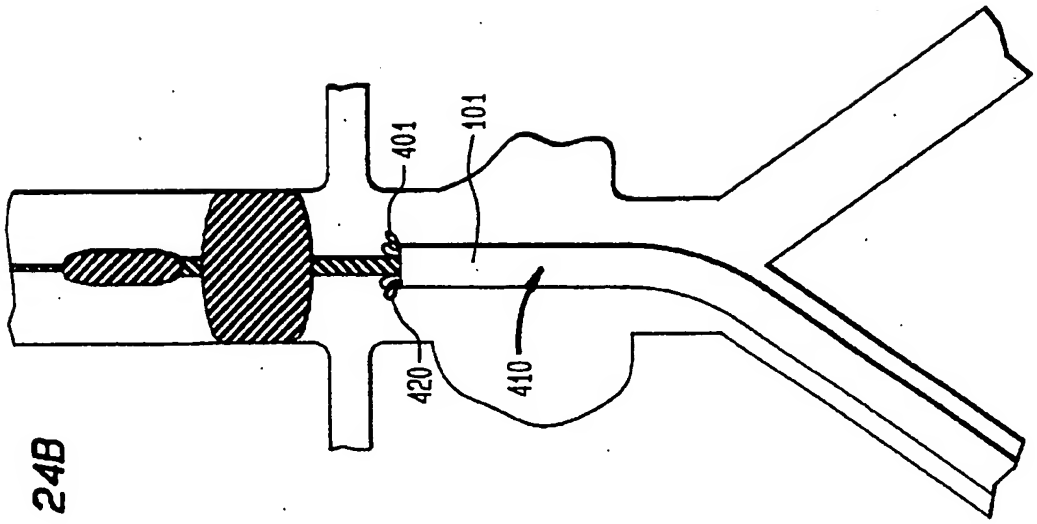



FIG. 24B

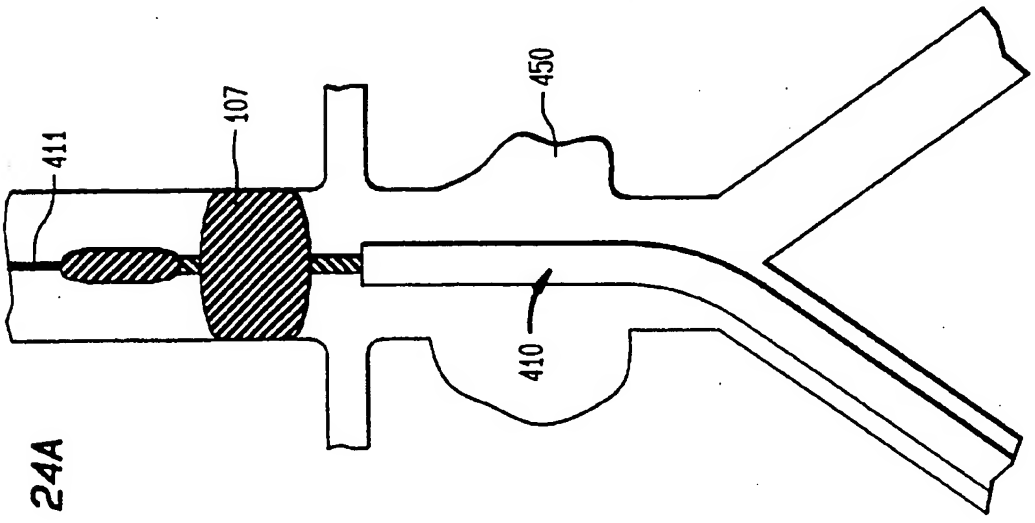



FIG. 24A

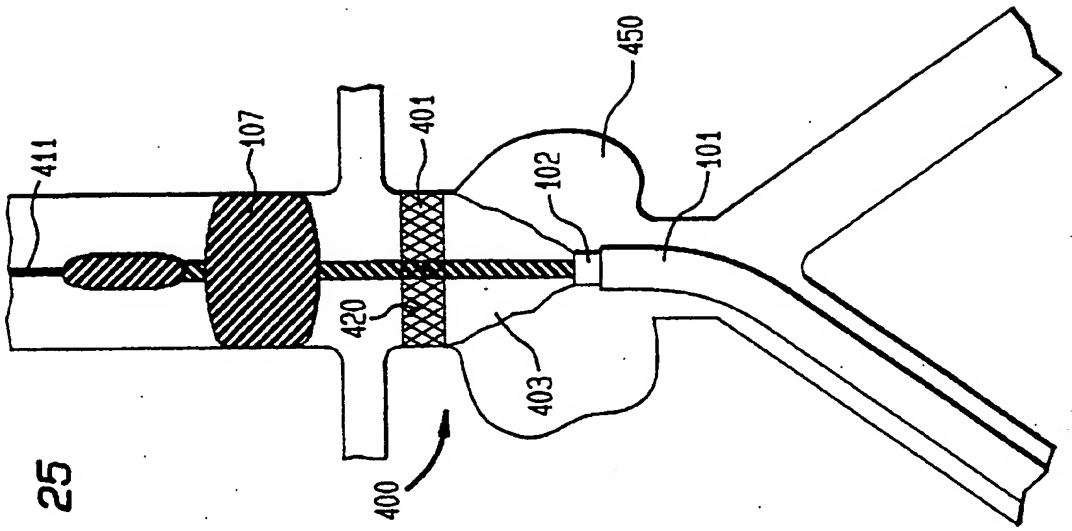



FIG. 25

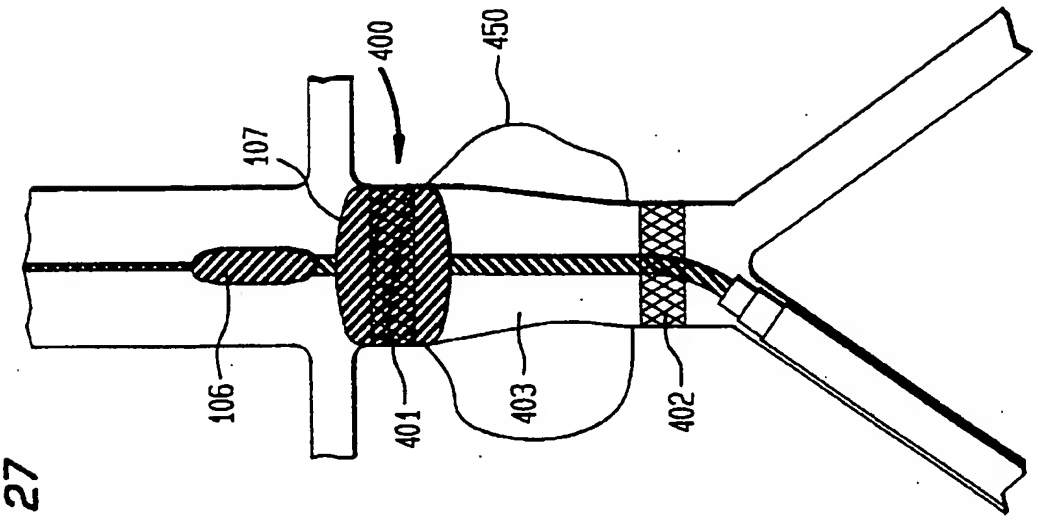



FIG. 27

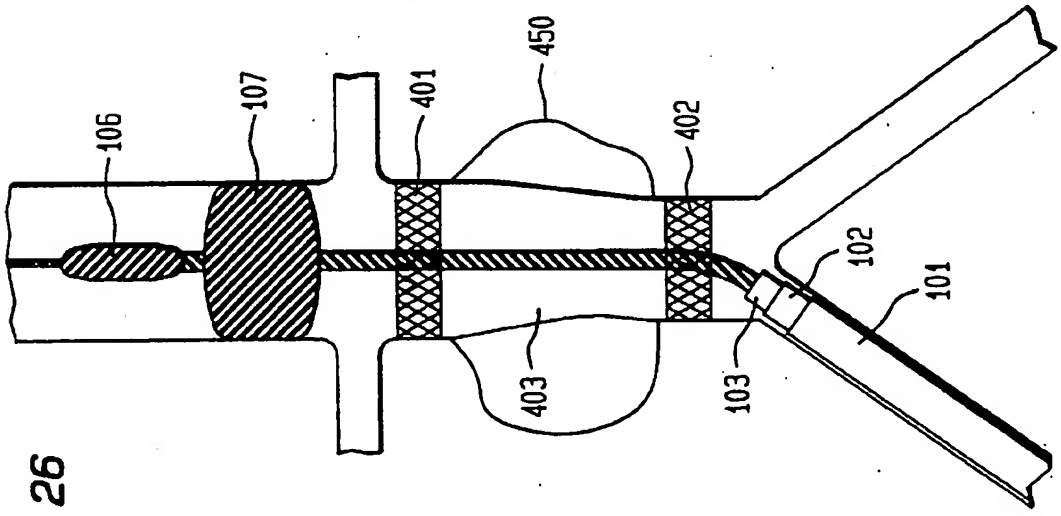



FIG. 26

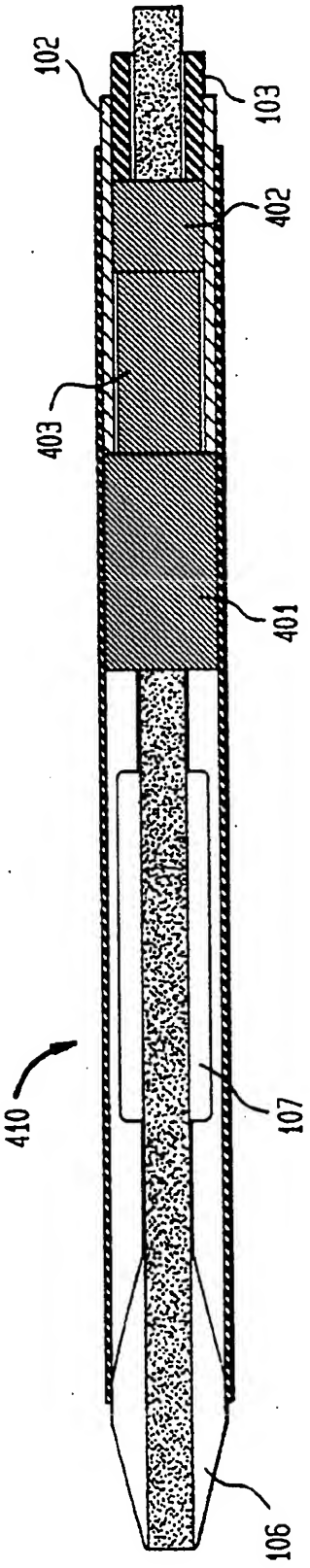

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FIG. 28

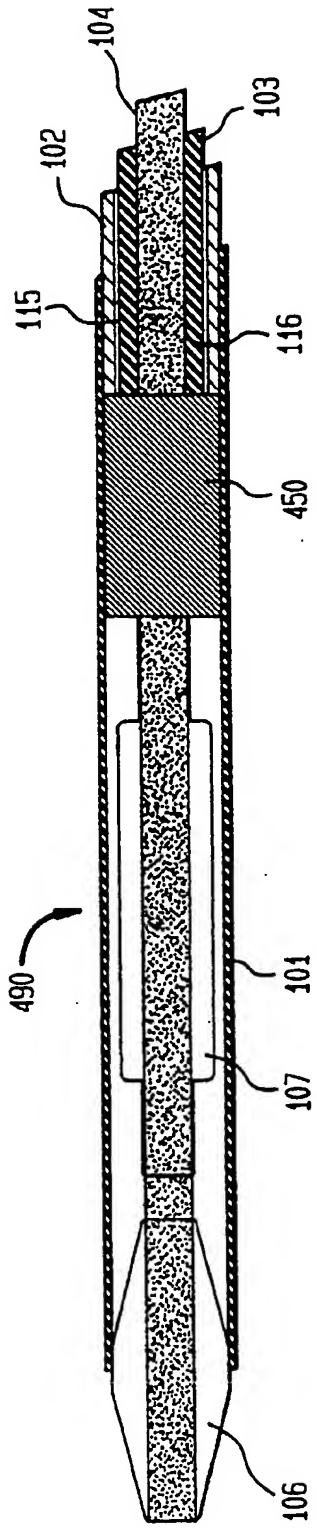
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FIG. 29

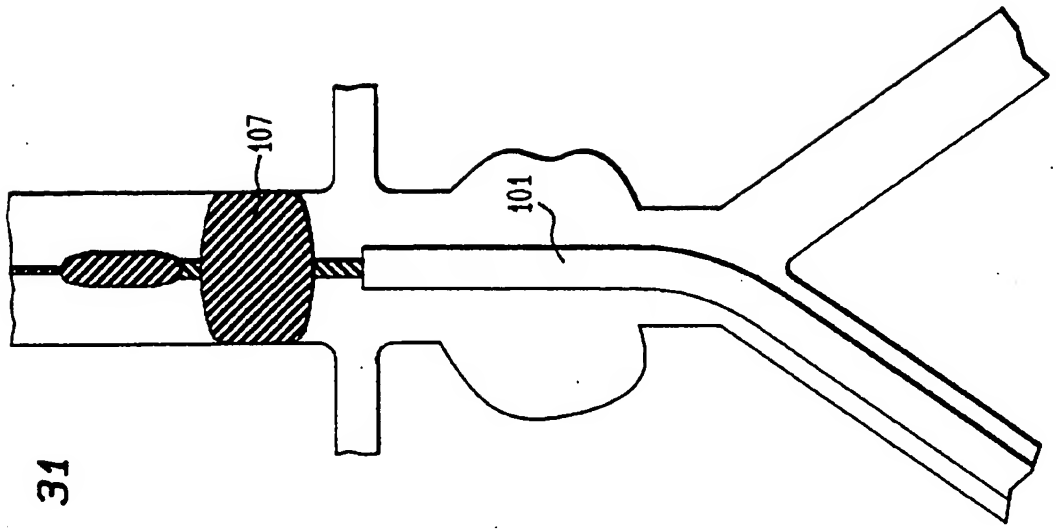


FIG. 31

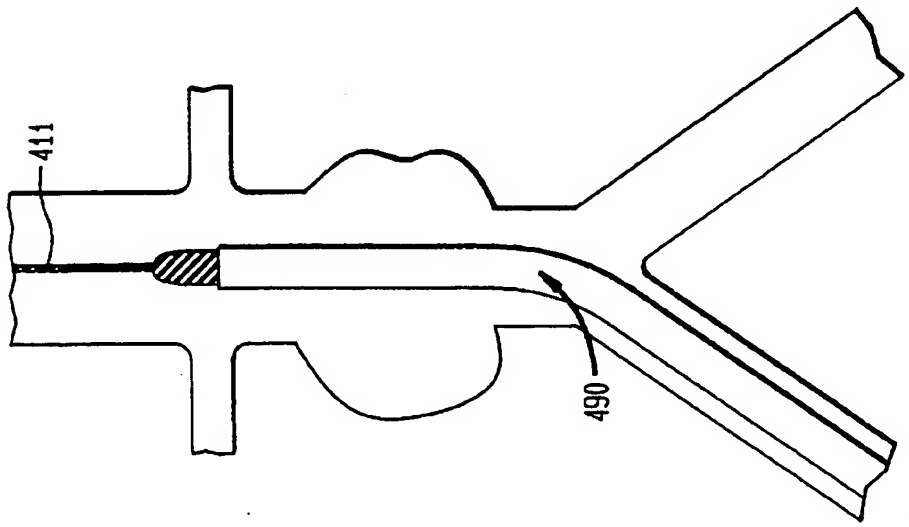


FIG. 30

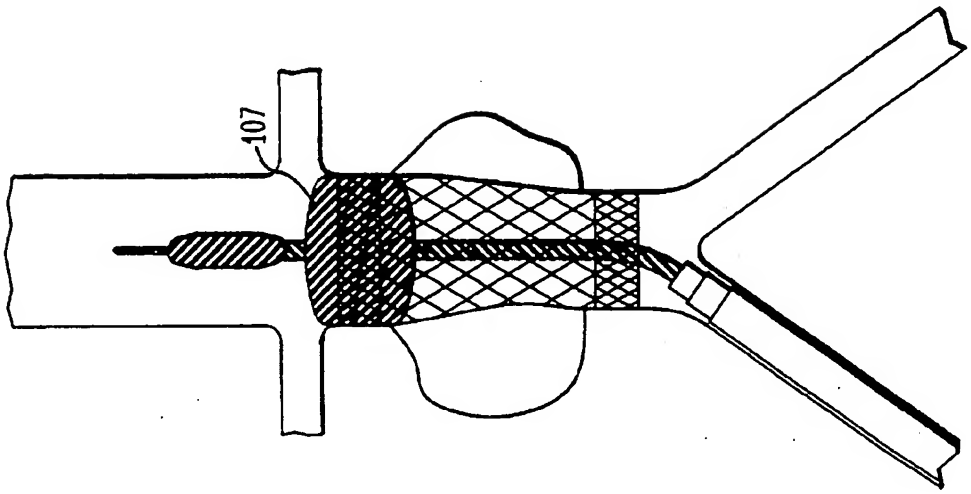


FIG. 34

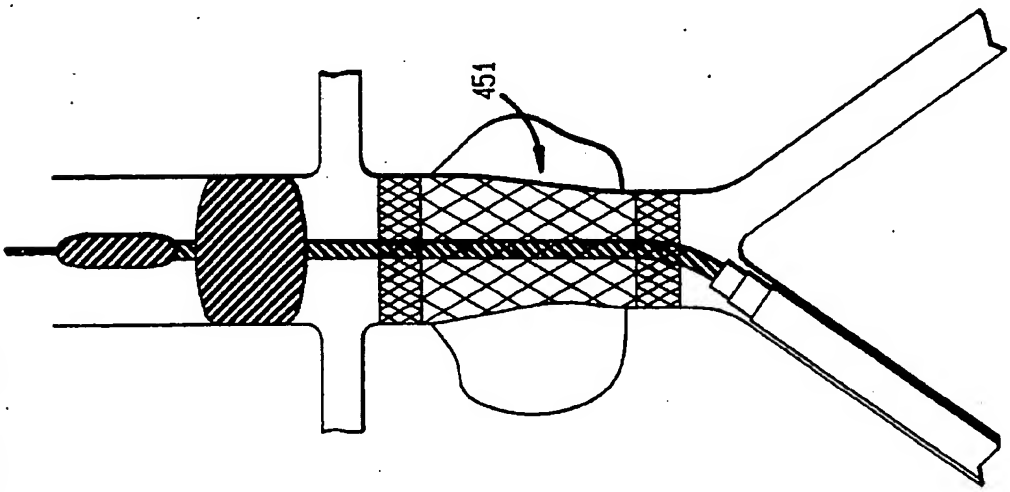


FIG. 33

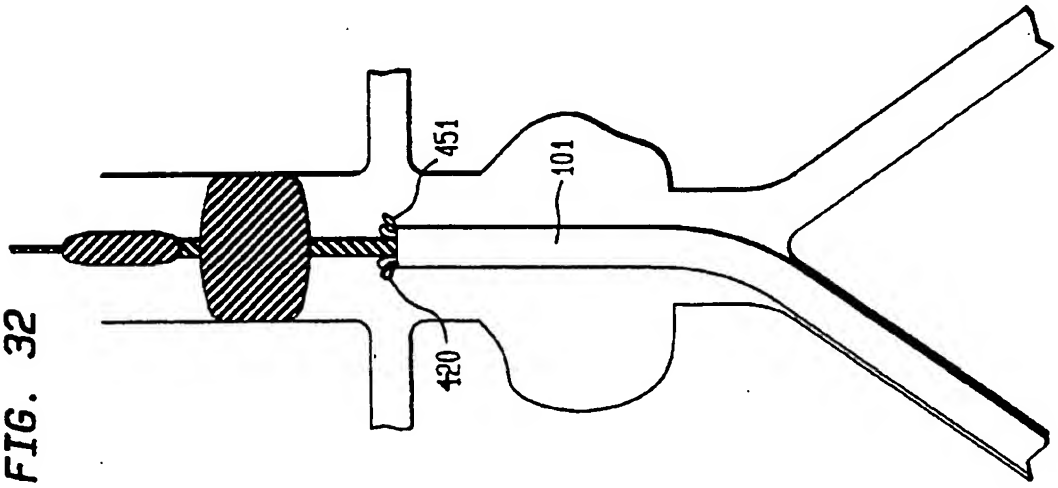


FIG. 32

# METHOD FOR DELIVERING A BIFURCATED ENDOLUMINAL PROSTHESIS

This is a continuation-in-part application of the application of common assignment herewith of inventors George Goicoechea, Claude Mialhe, John Hudson and Andrew Cragg, entitled BIFURCATED ENDOLUMINAL PROSTHESIS, filed on Sep. 27, 1994, application Ser. No. 08/312,881, pending.

## BACKGROUND OF THE INVENTION

The present invention relates to a bifurcated endoluminal prosthesis for use in a bifurcated blood vessel such, for example, as the infrarenal portion of a mammalian aortic artery where it bifurcates to the common iliac arteries. The present invention also embraces a stent connecting means for connecting a stent (e.g. a stent which forms part of an endoluminal prosthesis) to another stent, as well as apparatus and method for introducing prostheses to the vasculature and methods of treating angeological diseases.

A stent is used to provide a prosthetic intraluminal wall e.g. in the case of a stenosis to provide an unobstructed conduit for blood in the area of the stenosis. An endoluminal prosthesis comprises a stent which carries a prosthetic graft layer of fabric and is used e.g. to treat an aneurysm by removing the pressure on a weakened part of an artery so as to reduce the risk of embolism, or of the natural artery wall bursting. Typically, a stent or endoluminal prosthesis is implanted in a blood vessel at the site of a stenosis or aneurysm by so-called "minimally invasive techniques" in which the stent is compressed radially inwards and is delivered by a catheter to the site where it is required through the patient's skin or by a "cut down" technique in which the blood vessel concerned is exposed by minor surgical means. When the stent is positioned at the correct location, the catheter is withdrawn and the stent is caused or allowed to re-expand to a predetermined diameter in the vessel.

U.S. Pat. No. 4,886,062 discloses a vascular stent which comprises a length of sinuous or "zig-zag" wire formed into a helix; the helix defines a generally cylindrical wall which, in use, constitutes a prosthetic intraluminal wall. The sinuous configuration of the wire permits radial expansion and compression of the stent; U.S. Pat. No. 4,886,062 discloses that the stent can be delivered percutaneously and expanded in situ using a balloon catheter.

U.S. Pat. No. 4,733,665 discloses an expandable intraluminal graft which is constituted by a tubular member formed from a plurality of intersecting elongate members which permit radial expansion and compression of the stent.

EP-A-0556850 discloses an intraluminal stent which is constituted by a sinuous wire formed into a helix; juxtaposed apices of the wire are secured to one another so that each hoop of the helix is supported by its neighboring hoops to increase the overall strength of the stent and to minimize the risk of plaque herniation; in some embodiments the stent of EP-A-0556850 further comprises a tubular graft member to form an endoluminal prosthesis.

The prior art stents and prostheses mentioned above are generally satisfactory for the treatment of aneurysms, stenoses and other angeological diseases at sites in continuous unbifurcated portions of arteries or veins.

However, the prior art stents and prostheses are not wholly satisfactory for use where the site of desired application of the stent or prosthesis is juxtaposed or extends



across a bifurcation in an artery or vein such, for example, as the bifurcation in the mammalian aortic artery into the common iliac arteries. For example, in the case of an abdominal aortic aneurysm ("AAA") in the infrarenal portion of the aorta which extends into one of the common iliac arteries, the use of one of the prior art prosthesis referred to above across the bifurcation into the one iliac artery will result in obstruction of the proximal end of the other common iliac artery; by-pass surgery is therefore required to connect the one iliac artery in juxtaposition with the distal end of the prosthesis to the other blocked iliac artery. It will be appreciated by a person skilled in the art that it is desirable to avoid surgery wherever possible; the requirement for by-pass surgery associated with the use of the prior art prosthesis in juxtaposition with a bifurcation in an artery therefore constitutes a significant disadvantage.

## SUMMARY OF THE INVENTION

Throughout this specification, the term "proximal" shall mean "nearest to the heart," and the term "distal" shall mean "furthest from the heart."

According to one aspect of the present invention there is provided a stent connecting means for connecting two intraluminal stents one to the other to define a continuous lumen through the two stents, the stent connecting means including a first stent including a male engaging portion which can be compressed radially inwardly, and a second stent including a female cooperating portion. The male engaging portion may be entered into the female cooperating portion in a radially compressed state and thereafter caused or allowed to expand in the female cooperating portion; the arrangement being such that in service the interengagement of the male engaging portion and the female cooperating portion serves to resist longitudinal separation of the two stents one from the other.

Typically, the first stent may include a proximal male engaging portion; the second stent may include a distal female cooperation portion. The male engaging portion may be flared radially outwardly towards its extremity, and the female cooperating portion may be tapered radially inwardly towards its extremity. In some embodiments, the male engaging portion may comprise a frustoconical wall which flares outwardly towards its longitudinal extremity; the female engaging portion may comprise a frustoconical wall which tapers radially inwardly towards its longitudinal extremity.

Alternatively, said male engaging and female cooperating portions may be substantially untapered; they may be substantially cylindrical.

The male engaging portion of the first stent may be resiliently compressible in a radially inwards direction such that in the radially compressed state it is capable of self-reexpansion to engage in the female cooperating portion. Typically, each of said first and second stents may be resiliently compressible.

In use therefore the second stent may be delivered in a radially compressed state by using a catheter; when the second stent is located at the site of use, the catheter may be withdrawn thereby allowing the second stent to re-expand to engage the endoluminal surface of the blood vessel.

The first stent may then be delivered percutaneously or by a "cut down" technique to a site distal of the second stent such that the male engaging portion of the first stent in the radially compressed state is entered into the expanded female cooperating portion of the second stent; the catheter

may then be withdrawn allowing the first stent to re-expand such that the male engaging portion engages in the female cooperating portion of the second stent.

In some embodiments of the present invention the second stent may have two transversely spaced distal female cooperating portions; the second stent may therefore constitute a bifurcated stent for use in juxtaposition with a bifurcation in a blood vessel.

Each of the two transversely spaced distal female cooperating portions may be adapted for connection to a first male stent which, in use, extends across the bifurcation into a respective one of the branched blood vessels.

In a particular aspect of the present invention there is provided a bifurcated intraluminal stent for use in juxtaposition with an angeological bifurcation; the bifurcated intraluminal stent comprising a proximal portion adapted to be positioned in service in a blood vessel in juxtaposition with a bifurcation, a first distal stent portion adapted to extend across the bifurcation into one of the branched blood vessels and a second distal stent portion adapted to allow blood to flow from the proximal portion into the other branched vessel. The first distal stent portion may be formed integrally with the proximal portion.

In some embodiments the second distal stent portion may comprise a female cooperating portion which is adapted to engage a male engaging portion of a another stent adapted to extend in the other branched blood vessel such that, in use, the bifurcated stent can be connected in situ to the other stent. The bifurcated intraluminal stent may therefore constitute a second stent in accordance with the present invention comprising a distal female cooperating portion disposed intermediate the proximal and distal extremities of the stent; the other stent may constitute a first stent in accordance with the present invention.

Typically, the proximal end of said second stent may be flared radially outwardly towards its extremity to engage the endoluminal surface of the artery thereby to resist longitudinal movement of the second stent in service.

Each of the first and second stents may comprise a sinuous wire formed into a tubular configuration. The sinuous and tubular configurations may be imparted to the wire by winding it on a mandrel. Typically, each stent may be made from a shape memory nitinol (nickel-titanium) wire which may be wound on to the mandrel to form the stent in a tubular configuration of slightly greater diameter than the diameter of the blood vessel in which the stent is intended to be used. The stent may be annealed at an elevated temperature and then allowed to cool in air so that the nitinol wire "remembers" the configuration in which it was wound on the mandrel.

Said nitinol wire may be type "M" nitinol wire which is martensitic at temperatures below about 13° C. and is austenitic at temperatures above about 25° C.; it will be appreciated therefore that the type "M" wire will be austenitic at body temperature of 37° C. Typically, the annealing may be conducted at about 500° C. or more for at least about 60 minutes; after cooling the wire may be immersed in cold water to facilitate removal of the wire from the mandrel with the wire in its maleable martensitic form. Typically, the cold water may have temperature of less than about 10° C.; the wire may be immersed for about 5 minutes or more. An advantage of using nitinol wire to form the stent in accordance with the present invention is that the nitinol wire is "super elastic" in its austenitic state; the radial outward force exerted by the stent on the wall of the blood vessel in use is therefore substantially constant irrespective of the diameter of the vessel and the expanded stent.

In some embodiments the wire may have a helical configuration as disclosed in EP-A-0556850. Alternatively, the wire may be of an entirely novel configuration, namely one in which the wire forms a plurality of hoops such that the plane of the circumference of each hoop is substantially perpendicular to the longitudinal axis of the stent. Each hoop may comprise a substantially complete turn of the wire having a sinuous configuration; optionally, as each hoop is completed, the point of winding the wire may be displaced longitudinally with respect to the winding axis to form the next hoop. When the next hoop is complete, the point of winding is moved further longitudinally with respect to the winding axis to the form the next succeeding hoop and so on.

It will appreciated that an advantage of this novel arrangement is that the planes of the hoops are not skewed with respect to the longitudinal axis of the stent; the longitudinal ends of the stent are "square" to said longitudinal axis, so that when the stent is caused or allowed to expand in situ there is substantially no twisting of the stent as it shortens in length. It will be appreciated that this represents a significant advantage, as in areas of stenosis or aneurysm it is desirable to minimize the movement of the stent within the blood vessel so as to reduce the potential trauma to the patient. A stent of this configuration may be used, apart from the bifurcated embodiment otherwise taught herein, in any application which in stents generally have heretofor been used.

Typically, the stents of this invention whether of the helical or perpendicular variety, also comprise a securing means for securing an apex of the sinuous wire in one hoop to a juxtaposed apex of a neighboring hoop so that each hoop is supported by its neighbors. The securing means may comprise a loop element of a suture material, for example, to tie the juxtaposed apices together; the loop element may also comprise a loop formed of a thermoplastics material such, for example, as polypropylene. Alternatively, the securing means may be a bead formed of a thermoplastic material around juxtaposed apices. Also alternatively, the securing means may be a loop, ring, or staple formed of wire such as nitinol.

The male engaging portion and female cooperating portion, of the first and second interengaging stents of this invention, may be formed separately from the remainder of the respective non-engaging portions of these stents and then the engaging and non-engaging portions secured to one another by securing means.

In one embodiment of the present invention, the proximal and distal stent portions of the bifurcated stent in accordance with the present invention may be formed separately; the distal end of the proximal stent portion may be secured to the wider proximal end of a first intermediate frustoconical stent portion; the narrower distal end of the first intermediate frustoconical stent portion may be secured to the proximal end of the distal stent portion. The female cooperating portion of the bifurcated stent may be constituted by a second frustoconical stent portion which is secured to the distal end of the proximal stent portion in juxtaposition with the first frustoconical portion.

Alternatively the first and second frustoconical portions may be omitted; the proximal and distal stent portions may be secured directly one to the other.

The female cooperating portion may be constituted by a generally cylindrical stent portion secured to said proximal stent portion in transversely spaced relation to the distal portion.

Each of the first and second stents of the bifurcated form of the present invention may carry a tubular graft layer

formed from a biocompatible fabric in juxtaposition with the stent; the combined stent and graft layer constituting an endoluminal prosthesis. Typically the graft layer may be disposed externally of the stent; it will be appreciated however that in some embodiments the graft layer may be disposed internally of the stent. In some embodiments the graft layer may be secured to the stent by loop elements such, for example, as loops of polypropylene. The biocompatible fabric may be a polyester fabric or a polytetrafluoroethylene fabric; typically said fabric may be woven or a warp knitted polyester fabric. In some embodiments the woven or a warp knitted fabric may be formed in a seam-free bifurcated configuration as a sleeve for a bifurcated stent.

In some embodiments the male engaging portion of the first stent and the female cooperating portion of the second stent may be left uncovered. Alternatively, the fabric graft layer may extend to the proximal extremity on the external surface of the male engaging portion, and may be folded over the distal extremity of the female engaging portion to form an inner sleeve; in use the external fabric of the male engaging portion may butt against the folded over portion of the fabric internally of the female cooperating portion to form a substantially blood tight seal.

The present invention in one aspect therefore includes a bifurcated endoluminal prosthesis comprising a bifurcated stent in accordance with the invention and a tubular graft layer.

The first stent having the male engaging portion may also have a tubular graft layer. If required the first prosthesis may be introduced in a radially compressed state such that the male engaging portion of the first prosthesis is engaged in the intermediate female cooperating portion of the bifurcated prosthesis; the first prosthesis is then caused to be allowed to re-expand in situ such that the male engaging portion engages in the female cooperating portion to resist longitudinal separation of the two prosthesis in service.

The bifurcated prosthesis may be adapted for use in the infrarenal portion of a mammalian aorta in juxtaposition with the bifurcation of the common iliac arteries for the treatment of abdominal aortic aneurysms. In use the bifurcated endoluminal prosthesis may be introduced into the infrarenal portion of the aorta using a catheter such that the first distal stent portion extends into one of the branched iliac arteries; the catheter may then be withdrawn allowing the prosthesis to re-expand in situ.

It will be appreciated by a person skilled in the art that the prostheses may be introduced to the site of use percutaneously or by "cut down" techniques.

Any of the stents according to this invention may be provided on its external surface with circumferentially spaced wire barbs or hooks adapted to engage in the endoluminal surface of the host artery to resist longitudinal movement or slippage of the stent in use. Typically the barbs or hooks may be disposed on part of the stent which is provided with a fabric graft layer such that in use the points of the artery which are engaged by the barbs or hooks are covered by the fabric graft. It will be appreciated by a person skilled in the art that the trauma to the artery wall caused by the hooks or barbs may cause emboli; the provision of the fabric graft over the barbs or hooks in use will therefore help to prevent the introduction of such emboli into the blood stream.

The male engaging portion for the first stent may be provided with circumferentially spaced hooks or barbs on its external surface to engage the internal surface of said female cooperating means, thereby to reinforce the connecting means against longitudinal separation of the stents one from the other in the service.

The present invention therefore provides a connecting means for connecting two stents longitudinally one to the other. It will be appreciated that this represents a significant step forward in the art as it allows the provision of a bifurcated endoluminal prosthesis for use in juxtaposition e.g. with arterial bifurcations without requiring by-pass surgery to connect one of the branched arteries to the other branched artery.

In particular, the invention provides a bifurcated endoluminal prosthesis which can be positioned in an artery in juxtaposition with a bifurcation to extend into one of the branched arteries; the bifurcated prosthesis can be connected to another prosthesis which extends into the other branched artery. The prosthesis can be delivered percutaneously or by "cut down" methods and connected together in situ thereby to provide effective treatment of an angeological disease such, for example, as an aneurysm or a stenosis which extends across a bifurcation in a blood vessel without the need for by-pass surgery.

In another aspect, this invention provides an introducer for delivering, into the vasculature at an angeological bifurcation where a blood vessel branches into two branched vessels, a bifurcated endoluminal stent or prosthesis having a proximal portion adapted to be disposed in the blood vessel and a distal portion adapted to be disposed at least partially in one of the two branched vessels. The introducer comprises a tubular outer sheath, a proximal portion pusher disposed at least partially within the outer sheath, and a distal portion pusher disposed at least partially within the proximal portion pusher.

The present invention further provides an introducer for delivering into the vasculature at an angeological bifurcation where a blood vessel branches into two branched vessels, an endoluminal prosthesis having a proximal stent portion and a distal stent portion. The introducer comprises a tubular outer sheath, a proximal portion pusher disposed at least partially within the outer sheath and having a proximal end adapted to contact the proximal stent portion, a distal portion pusher disposed at least partially within the proximal portion pusher and having a proximal end adapted to contact the distal stent portion; and a balloon catheter, having a balloon attached thereto, disposed at least partially within the distal portion pusher.

This invention in another aspect provides a method for delivering a bifurcated endoluminal stent or prosthesis having a proximal portion and a first distal portion into the vasculature at an angeological bifurcation where a blood vessel branches into a first branched vessel and a second branched vessel. The method comprises inserting a first introducer containing the stent or prosthesis into the vasculature to a predetermined delivery location, the first introducer comprising an outer sheath, a proximal portion pusher, and a distal portion pusher; withdrawing the outer sheath of the first introducer while maintaining the proximal portion pusher in a fixed position until the proximal portion of the stent or prosthesis is deployed from the first introducer into the blood vessel; withdrawing the outer sheath and the proximal portion pusher while maintaining the distal portion pusher in a fixed position until the first distal portion of the stent or prosthesis is deployed from the first introducer at least partially into the first branched vessel; and withdrawing the first introducer from the vasculature.

This invention further provides a method for delivering, into the vasculature at an angeological bifurcation where a

blood vessel branches into two branched vessels, an endoluminal prosthesis having a proximal stent portion, and a distal stent portion. The method comprises the steps of inserting an introducer containing the prosthesis into the vasculature to a predetermined delivery location, the introducer comprising an outer sheath, a proximal stent portion pusher, a distal stent portion pusher, and a balloon catheter having a balloon attached thereto; inflating the balloon to at least partially block blood flow in the blood vessel; withdrawing the outer sheath of the introducer while maintaining the proximal stent portion pusher in a fixed position until the proximal stent portion of the prosthesis is deployed from the introducer into the blood vessel; withdrawing the outer sheath and the proximal stent portion pusher while maintaining the distal stent portion pusher in a fixed position until the distal stent portion of the prosthesis is deployed from the introducer into the blood vessel; and withdrawing the introducer from the vasculature.

In general, this invention provides a method of treating an angeological disease at a bifurcation site where a blood vessel branches into a first branched vessel and a second branched vessel comprising the steps of disposing in the blood vessel a proximal portion of an endoluminal stent; directing blood flow from the blood vessel into the first branched vessel through a first distal portion of the endoluminal stent, the first distal portion being connected to the proximal portion and extending into the first branched vessel; and directing blood flow from the blood vessel into the second branched vessel through a second distal portion of the endoluminal stent, the second distal portion being connected to the proximal portion and extending into the second branched vessel. This method may be applied to aneurysms, occlusions, or stenosis.

Following is a description by way of example only and with reference to the accompanying drawings of the present invention, including novel stent constructions and methods of manufacture and use thereof.

## BRIEF DESCRIPTION OF THE DRAWINGS

The aspects, features and advantages of the present invention will be more readily understood from the following detailed description when read in conjunction with the accompanying drawings, in which:

FIG. **1***a* is a front view of a bifurcated intraluminal stent in accordance with the present invention constituting part of an endoluminal prosthesis.

FIG. **1***b* is a front view of another stent which is adapted to be connected to the bifurcated stent of FIG. **1***a*.

FIG. **2**(*a*) is a side view of part of the bifurcated stent of FIG. **1***a* opened up to show its construction.

FIG. **2**(*b*) is a side view of an exemplary mandrel used to form the part of the bifurcated stent shown in FIG. **2** (*a*).

FIG. **3** is a side view of another part of the bifurcated stent of FIG. **1***a* opened up to show its construction.

FIG. **4**(*a*) is a side view of yet another part of the bifurcated stent of FIG. **1***a* opened up to show its construction.

FIGS. **4**(*b*)–**4**(*f*) are partial exploded views of the exemplary stent of FIG. **4**(*a*) illustrating alternative means for securing juxtaposed apices according to the present invention.

FIG. **5** is a schematic perspective view of a bifurcated endoluminal prosthesis in accordance with the present invention.

FIG. **6** is a schematic view of another bifurcated endoluminal prosthesis in accordance with the present invention.

FIG. **7** is a schematic view of yet another bifurcated endoluminal prosthesis in accordance with the present invention.

FIG. **8**(*a*) is a cross-sectional view of an exemplary assembled introducer according to the present invention.

FIGS. **8**(*b*)–**8**(*e*) are side views of the component parts of the introducer of FIG. **8**(*a*).

FIG. **8**(*f*) is a partial cross-sectional view of the introducer of FIG. **8**(*a*).

FIG. **8**(*g*) is a cross-sectional view of part of the introducer of FIG. **8**(*f*) taken along the line A—A.

FIG. **9** is a side cross-sectional view of a portion an alternative embodiment of an introducer according to the present invention.

FIGS. **10**(*a*) and **10**(*b*) are side views of other alternative embodiments of an introducer according to the present invention.

FIGS. **11** through **20** are sequential cross-sectional views of the bifurcation of the abdominal aortic artery during introduction of an exemplary prosthesis according to the present invention.

FIGS. **21**(*a*)–**21**(*c*) are cross-sectional views of alternative insertion apparatus according to the present invention.

FIGS. **22** and **23** are side views of alternative stents according to the present invention.

FIGS. **24**(*a*), **24**(*b*), **25**, **26** and **27** are sequential cross-sectional views of the bifurcation of the abdominal aortic artery during introduction of an exemplary prosthesis according to the present invention.

FIGS. **28** and **29** are cross-sectional side views of alternative delivery apparatus according to the present invention.

FIGS. **30**–**34** are sequential cross-sectional views of the bifurcation of the abdominal aortic artery during introduction of an exemplary prosthesis according to the present invention.

## DETAILED DESCRIPTION

The present invention includes apparatus and method for treating angeological diseases in any bifurcated blood vessel. One example of such a bifurcated blood vessel is the infrarenal portion of a mammalian aortic artery where it bifurcates to the common iliac arteries. Examples of diseases that can be treated using the apparatus and method of the present invention include aneurysm, stenosis, and occlusion.

A bifurcated stent in accordance with the present invention which is indicated at **10** in FIG. **1***a* comprises a wire skeleton which is constructed in four separate parts, namely a proximal part **12**, a first frustoconical part **14**, a first distal part **16** and a second frustoconical part **18**. Said bifurcated stent **10** carries a fabric graft layer (FIGS. **5**, **6**, and **7**) for use as an endoluminal prosthesis e.g. in the infrarenal portion of a mammalian aorta in juxtaposition with the bifurcation of the common iliac arteries. It will be appreciated, however that bifurcated stents (with or without fabric graft layers) for use in different parts of the angeological system and for different mammals can be constructed in accordance with the invention by varying the dimensions of the stent accordingly.

Each of the four parts of the bifurcated stent **10** is made in substantially the same way by winding a shape memory nitinol wire, typically nitinol type M wire, onto a mandrel **46**.

The construction of the exemplary proximal part **12** of the bifurcated stent **10** is shown in FIGS. **2**(*a*) and **2**(*b*); nitinol wire type M wire typically having a diameter of 0.46 mm (0.018") is wound around mandrel **46** to form a plurality of hoops **20**. The winding surface of mandrel **46** is provided with a plurality of upstanding pins **47** disposed in a zig-zag pattern for each of the hoops **20** so that in each hoop **20** the nitinol wire follows a sinuous path to define a plurality of circumferentially spaced apices **22**. Each hoop **20** is wound onto mandrel **46** such that the plane of the circumference of each hoop **20** is substantially perpendicular to the longitudinal axis of the mandrel.

When one hoop **20** e.g. the hoop indicated at **20***a* has been formed, the point of winding of the nitinol wire is displaced longitudinally with respect to the axis of mandrel **46** to form the next successive hoop **20***b*. The stent shown in FIG. **2**(*a*) is the stent formed on mandrel **46** shown in FIG. **2**(*b*) after cutting the stent longitudinally and rotating it 45 degrees to show the construction of the stent.

The proximal part of the exemplary bifurcated stent of FIG. **1***a* is formed on the mandrel with a diameter of about 24 mm and a length in the longitudinal direction of about 55 mm. From FIGS. **1**(*a*), **2**(*a*), and **2**(*b*) it will be noted that the proximal part **12** is constituted by three hoops **20** of unit width at the proximal end **24** of the proximal part **12**, two intermediate hoops **25** of twice unit width and, at its distal end **26**, by a single hoop **20** of unit width. In the illustrated embodiment, intermediate hoops **25** have a plurality of offsets **25***a*. Offsets **25***a* are formed when the wire is passed around pins **47** on mandrel **46**. Offsets **25***a* add stability to the stent. When the nitinol wire has been wound onto mandrel **46**, the nitinol wire is annealed at an elevated temperature and then allowed to cool.

In this embodiment of the invention the wire is annealed at a temperature of about 500° C. for 60 minutes and is then allowed to cool in air. The purpose of the annealing is so that the nitinol wire in its austenitic form "remembers" its configuration as wound on mandrel **46**; it will be appreciated therefore that other temperatures and durations for the annealing are included within the present invention provided the nitinol wire "remembers" its wound configuration.

After annealing and cooling, the wire is immersed in cold water at less than 10° C. for about 5 minutes; the wire is then removed from the mandrel, and juxtaposed apices **22** of neighboring hoops **20** are secured together by securing means **99** (see FIG. **4**(*a*)), which are, in this example, 0.003" polypropylene filaments. Each apex **22** of each hoop **20** which has a juxtaposed apex of a neighboring hoop **20** is tied to the juxtaposed apex **22**. It will be appreciated, however, that in other embodiments of the invention only some of the juxtaposed apices **22** may be secured in this way.

In addition to polypropylene filaments, the securing means may comprise a loop element **99***a* of a suture material, for example, to tie the juxtaposed apices together, as shown in FIG. **4**(*b*). The securing means may also comprise bead **99***b* formed of a thermoplastic material around juxtaposed apices, as shown in FIG. **4**(*c*). Also alternatively, the securing means may be a loop **99***c*, ring **99***d*, or staple **99***e* formed of wire such as nitinol, as shown in FIGS. **4**(*d*), **4**(*e*), and **4**(*f*) respectively.

The exemplary first and second frustoconical parts **14**, **18** of the skeleton shown in the figures are formed in substantially the same way as the proximal part **12** by winding nitinol wire onto a mandrel and then annealing the wire before removing it from the mandrel. As shown in FIG. **3**, the first and second frustoconical parts **14**, **18** are each constituted by three hoops **20** of unit width. The mandrel is tapered such that the proximal end of each of the exemplary frustoconical parts **14**, **18** is formed with a diameter of about 12 mm and the distal end **32** of each is formed with a diameter of about 9 mm. The overall length of each of the exemplary frustoconical parts **14**, **18** is about 18 mm. The wire used for the frustoconical parts **14**, **18** is nitinol type M wire having a diameter of 0.28 mm (0.011"). Juxtaposed apices **22** of each of the exemplary frustoconical parts **14**, **18** are tied together using 0.03" polypropylene filaments as described above. The first and second frustoconical parts **14**, **18** are secured to the distal end **26** of the proximal part **12** of the stent **10** in transversely spaced relation as shown in FIG. **1***a* by securing the apices **22** of the hoop **20** forming the wider proximal end **30** of each of the frustoconical parts **14**, **18** to juxtaposed apices **22** of the hoop **20** on the distal end **26** of the proximal part **12**.

The exemplary first distal part **16** of the bifurcated stent **10** is formed by winding nitinol type M wire typically having a diameter of 0.28 mm (0.011") onto a mandrel to form twelve longitudinally spaced hoops **20** as shown in FIG. **4**; the exemplary first distal part has an overall length of about 66 mm and a uniform diameter of about 9 mm. The proximal end **34** of the distal part **16** is secured to the narrower distal end **32** of the first frustoconical part **14** by tying each apex **22** on the proximal end **34** of the first distal part **16** to a juxtaposed apex on the distal end **32** of the first frustoconical part **14** using, in this embodiment, 0.003" polypropylene filaments.

The proximal part **12**, the first and second frustoconical parts **14**, **18**, and the first distal part **16** are each covered with a tubular graft layer of a biocompatible woven fabric (FIGS. **5**, **6**, and **7**) such, for example, as a plain woven fabric made from 30 or 40 denier polyester. The tubular fabric layers may be attached to the proximal and distal parts **12**, **16** of the stent **10** by stitching with, for example, 0.003" polypropylene filaments around the apices **22** of the underlying skeleton. The fabric covered stent constitutes one form of an endoluminal prosthesis.

The proximal part **12** of the wire skeleton may be provided with a plurality of circumferentially spaced hooks or barbs **43** which project through the tubular fabric layer to engage in the endoluminal surface of a host artery in service.

The sinuous configuration of each turn **20** of the wire skeleton of the stent **10** allows the prosthesis to be compressed resiliently radially inwards so that it can be received in a catheter e.g. a 16 or 18 French catheter for percutaneous or cut down delivery, e.g. to an intraluminal site in the infrarenal section of the aortic artery. Larger diameter catheters up to, e.g., 20 French, may be used to deliver the prosthesis using "cut down" procedures.

An x-ray opaque marker may be attached to one or more ends of a stent so that the delivery of the stent can be monitored using x-rays. As shown in FIG. **4**(*a*), such a radiopaque marker may typically comprise a gold or platinum wire **17** crimped onto an end of stent **16**. Alternatively, the radiopaque marker may be a tube **17***a* disposed around a length of wire on the stent, also as shown in FIG. **4**(*a*). Typically, in the bifurcated stent the marker is secured to the stent in line with the distal stent portion so that the distal stent portion can be aligned with and inserted into one of the branched arteries in situ.

The bifurcated endoprosthesis is positioned in the infrarenal section of the aortic artery in juxtaposition with the bifurcation of the common iliac arteries such that the first distal part **16** of the prosthesis extends into one of the

common iliac arteries. The catheter is then withdrawn allowing the stent **10** to re-expand towards its configuration as wound on the mandrel in which it was annealed until the stent engages the endoluminal surface of the host artery. The barbs or hooks engage the endoluminal surface of the host artery to resist longitudinal displacement or slipping of the prosthesis in use.

It will be appreciated that when the bifurcated prosthesis is positioned and re-expanded in the fitted position, blood can flow from the aortic artery into the proximal part **12** of the prosthesis from where it can flow into the one common iliac artery through the frustoconical part **14** and the first distal part **16** and also into the other common iliac artery through the second frustoconical part **18**.

In cases where it is required to implant a prosthesis in the other common iliac artery a second prosthesis comprising a second stent **40** as shown in FIG. **1***b* can be used. The second stent **40** includes a wire skeleton comprising a proximal frustoconical part **42** and a distal part **44**. The distal part **44** of the second stent **40** also may be covered with a tubular graft layer of a biocompatible fabric such, for example, as polyester or polytetrafluoroethylene fabric (FIGS. **5**, **6**, and **7**).

The frustoconical proximal part **42** is constructed in the same way as the frustoconical parts **14**, **18** of the bifurcated stent **10**; the distal part **44** is constructed in the same way as the distal part **16** of the bifurcated stent **10**. The distal end of the frustoconical proximal part **42** is secured to the proximal end of the distal part **44** by securing juxtaposed apices using polypropylene filaments as described above.

In use, the second prosthesis is compressed radially inwards and is received in a catheter for percutaneous or "cut down" delivery to the other common iliac artery. The frustoconical proximal part **42** is guided, in the radially compressed state, into the second frustoconical part **18** of the bifurcated stent **10**. The catheter is then withdrawn allowing the second stent **40** to re-expand towards its remembered configuration, until the distal part **14** engages the endoluminal surface of the other common iliac artery, and the outer surface of the frustoconical proximal part **42** engages the interior surface of the second frustoconical part **18** of the bifurcated stent **10**.

As with other stents described herein, the frustoconical proximal part **42** may be formed with circumferentially spaced barbs or hooks **43**, as shown in FIG. **1***b*, which engage in the wire skeleton of the second frustoconical part **18** of the bifurcated stent **10**. When barbs **43** are on proximal portion **12**, they engage the inner wall of the artery.

The tapered configurations of the second frustoconical part **18** of the bifurcated stent **10** and of the proximal frustoconical part **42** of the second stent **40** are such that in the fitted position as described, the prosthesis are locked together to resist longitudinal separation in service. Barbs or hooks on the second stent **40** and/or an frustoconical proximal part **42** help to resist such longitudinal separation.

In another example of the present invention a bifurcated endoluminal prosthesis **50** as shown in FIG. **5** includes a bifurcated stent comprising a proximal portion **52** which tapers radially inwardly from its proximal end **54** to its distal end **56**, and first and second transversely spaced frustoconical distal portions **58**, **60** which are secured to the distal end **56** of the proximal portion **52**; the proximal portion **52** is covered with a tubular graft layer of a biocompatible fabric **62**.

In use the prosthesis is delivered percutaneously or by "cut down" methods to an artery in juxtaposition with an arterial bifurcation; blood can flow through the frustoconical proximal portion **52** into each of the branched arteries through the first and second distal frustoconical portions **58**, **60**. If a prosthesis is required in one or both of the branched arteries, a separate prosthesis comprising a stent of the type shown in FIG. **1***b* referred to above covered with fabric can be connected to the bifurcated prosthesis **50** by inserting and re-expanding the proximal end of such a separate prosthesis in one or both of the distal frustoconical portions **58**, **60** of the prosthesis **50** for engagement therein.

Another variant of the present invention is shown in FIG. **6** which shows a bifurcated endoluminal prosthesis **70** having a proximal portion **72** which is secured at its distal end **74** to two transversely spaced frustoconical intermediate portions **76**, **78**.

One of said frustoconical intermediate portions **76** is secured at its distal end to an elongate distal portion **80**. The proximal end **82** of the proximal portion **72** is flared radially outwards towards its proximal end **82** to engage the intraluminal surface of the host blood vessel in service. Save for this flared portion, the entire endoprosthesis is covered with a fabric graft layer as shown in FIG. **6**; said graft layer is carried externally of the wire skeleton and is folded over the distal extremity **84** of the other frustoconical intermediate portion **78** to form an internal lining in said other frustoconical immediate portion **78**.

Said other frustoconical intermediate portion **78** constitutes a female cooperating portion in accordance with the present invention which is adapted to receive a male engaging portion of another prosthesis as indicated at **86** in FIG. **6**. Said other prosthesis **86** includes a frustoconical proximal portion **88** which constitutes the male engaging portion and an elongate distal portion **90**. The whole of the other prosthesis **86** is covered with a fabric graft layer as shown in FIG. **6**. In service, the male engaging portion **88** of the other prosthesis **86** is entered into and engaged with the female cooperating portion **78** of the bifurcated prosthesis **70** in situ in the manner herein before described. The fabric layer on the male engaging portion **88** butts face-to-face on the folded over portion of the fabric layer disposed internally of the female cooperating portion **78** to form a substantially blood-tight seal therewith.

Yet another example of the present invention is shown in FIG. **7** in which a bifurcated endoluminal prosthesis **91** has a generally cylindrical proximal portion **92**; said proximal portion **92** is connected at its distal end **93** to an elongate, generally cylindrical distal portion **94**. Said proximal portion **92** is also connected at its distal end **93** to a generally cylindrical intermediate portion **95** which is secured in transversely spaced relation to the elongate distal portion **94**. Said cylindrical intermediate portion **95** constitutes a female engaging portion which is adapted to receive a generally cylindrical male engaging portion of a second elongate prosthesis (not shown). The male engaging portion is equipped with circumferentially spaced external barbs to engage in the female cooperating portion in service. As shown in FIG. **7**, the whole of the bifurcated prosthesis **91** is covered with an external fabric graft layer save for a flared portion **96** towards the proximal end **97** of the proximal portion **92**.

Referring to FIGS. **8**(*a*)–**8**(*f*), an exemplary embodiment of a delivery system according to the present invention will be described. This system is used to deploy the bifurcated stent **10** when it is covered with a fabric graft layer to create an endoluminal prosthesis. Introducer **100** includes outer sheath **101**. Outer sheath **101** is a cylindrical tube adapted to

be inserted either percutaneously or by "cut-down" procedures into the vasculature from an entry point to the bifurcation site where the prosthesis is to be deployed.

Housed within outer sheath **101** is proximal portion pusher **102**. Proximal portion pusher **102** is a cylindrical tube having an outside diameter smaller than the inside diameter of outer sheath **101**. Proximal portion pusher **102** is preferably slidable throughout the length of outer sheath **101**.

Disposed within proximal portion pusher **102** is distal portion pusher **103**. Distal portion pusher **103** is a cylindrical tube slidably contained within distal portion pusher **102**. Distal portion pusher **103** is preferably adapted to slide throughout the entire length of proximal portion pusher **102**.

Disposed within distal portion **103** is balloon catheter **104**. Balloon catheter **104** is adapted to slide within distal portion pusher **103**. At the leading end **105** of balloon catheter **104** is nose cone **106**. Balloon **107** is attached to balloon catheter **104** between nose cone **106** and proximal end **115** of proximal portion pusher **102**.

As shown in FIG. **8**(*g*), which is a cross-sectional view of balloon catheter **104** in the direction A—A of FIG. **8**(*f*), balloon catheter **104** has a guide wire conduit **104***a*. Guide wire conduit **104***a* extends throughout the length of balloon catheter **104** for passing a guide wire (not shown) through introducer **100**. In the illustrated embodiment, balloon catheter **104** also includes injection orifice **109** and an injection conduit **109***a*. Injection conduit **109***a* connects injection orifice **109** to an injection site **108** at or near the distal end of balloon catheter **104** as shown in FIG. **8**(*e*). Radiopaque liquid may be injected into injection site **108**, through injection conduit **109***a*, out injection orifice **109**, and into the vasculature to monitor deployment of the prosthesis.

Also in the illustrated embodiment of FIGS. **8**(*f*) and **8**(*g*), balloon catheter **104** has an inflation orifice **110** located at a point where balloon **107** is attached to balloon catheter **104**. A balloon inflation conduit **110***a* connects balloon inflation orifice **110** to balloon inflation site **111** (FIG. **8**(*e*)). Balloon **107** may be inflated and deflated from balloon inflation site **111** during delivery of the prosthesis.

In an alternative embodiment illustrated in FIG. **9**, seals **150**, **151** may be disposed around the distal ends **160**, **161** of outer sheath **10** and proximal portion pusher **102**. Seals **150**, **151** may be formed of silicone tubes.

FIG. **10**(*a*) shows an alternative embodiment of introducer **100**. As shown in FIG. **10**(*a*), wings **112** and **113** are provided at the distal end of introducer **100**. Wing **112** is connected to proximal portion pusher **102**, and wing **113** is connected to outer sheath **101**. Wings **112** and **113** indicate the rotational orientation of proximal portion pusher **102** and outer sheath **101**, respectively. This in turn indicates the orientation of proximal portion **12** within outer sheath **101** and distal portion **16** within proximal portion pusher **102**. Wings **112** and **113** in the illustrated embodiment are also provided with holes **112***a* and **113***a*.

As shown in FIG. **10**(*b*), a rod **128** or other fixation device may be attached to wings **112** and **113** using e.g. bolts through holes **112***a* and **113***a* secured by wing nuts **129** or other securing means. Rod **128** prevents relative movement of proximal portion pusher **102** and outer sheath **101**. Wings may also be provided on distal portion pusher **103** and used to secure distal portion pusher **103** to either proximal portion pusher **102** or outer sheath **101** using a fixation device as described above.

Also shown in FIG. **10**(*a*) as part of introducer **100** is hemostasis valve **114**. Hemostasis valve **114** is connected to distal portion pusher **103** and acts as a simple seal around balloon catheter **104**. Although it prevents fluid loss, hemostasis valve **114** allows balloon catheter **104** to slide within distal portion pusher **103**. Alternatively, a Touhy-Borst valve (not shown) may be used instead of hemostasis valve **114**. The Touhy-Borst valve is a device that may be manually tightened over balloon catheter **104**. Lightly tightening such a valve permits balloon catheter **104** to slide; firmly tightening such a valve clamps balloon catheter **104** in place.

In use, the prosthesis must first be loaded into introducer **100**. Outer sheath **101** is first removed from introducer **100**. Balloon catheter **104** is then threaded through distal portion **16** and proximal portion **12** of the prosthesis. The prosthesis is then cooled to a temperature of approximately 10° C. or below and radially compressed. For this purpose, the prosthesis may be immersed in cold water. The prosthesis should preferably remain in the water during the loading operation.

As supporting stent **10** is compressed beneath the fabric covering of the prosthesis, excess fabric is produced. This excess fabric may simply be pinched together and laid over the compressed prosthesis in longitudinal folds.

Distal portion **16** of the prosthesis in the radially compressed state is then inserted into proximal portion pusher **102**. Outer sheath **101** is then pulled over proximal portion **12** of the prosthesis and over proximal portion pusher **102**. A thread (not shown) may be attached to the proximal end of proximal portion **12** of the prosthesis and threaded through outer sheath **101**. This thread may then be used to pull proximal portion **12** through outer sheath **101**. During the loading process, it is important to keep proximal portion **12** and distal portion **16** of the prosthesis properly aligned with outer sheath **101** and proximal portion pusher **102**. Marks may be placed on the outside of outer sheath **101** and proximal portion pusher **102** to ensure proper alignment.

Referring again to FIG. **8**(*f*), the prosthesis is inserted such that the outer surface of proximal portion **12** contacts and is radially restrained by outer sheath **101**, and the outer surface of distal portion **16** contacts and is radially restrained by proximal portion pusher **102**. End **115** of proximal portion pusher **102** longitudinally engages proximal portion **12** of the prosthesis as shown in FIG. **8**(*f*).

Balloon catheter **104** is positioned such that nose cone **106** just clears proximal end **117** of outer sheath **101**. The introducer is now in condition for insertion into the patient.

Referring to FIG. **11**, introducer **100** is passed through an entry point (not shown) either in the patient's skin (percutaneous operation) or into the vasculature itself which has been surgically exposed ("cut-down" operation). Introducer **100** is inserted over a guide wire **170** into the vasculature from the entry point to the desired delivery location at an angeological bifurcation.

In the aorta, introducer **100** is positioned such that end **117** of outer sheath **101** is approximately level with renal arteries **180** as shown in FIG. **11**. Balloon catheter **104** is then extended while maintaining outer sheath **101** in a fixed position. Balloon catheter **104** in this embodiment is extended until distal end **105** of nose cone **106** is approximately 35 mm above the proximal tip **117** of outer sheath **101**. Then, while maintaining proximal portion pusher **102** in a fixed position, outer sheath **101** is withdrawn until the proximal tip of the prosthesis is level with proximal tip **117** of outer sheath **101**. It will be noted that balloon catheter **104** does not move while outer sheath **101** is so withdrawn.

Introducer **100** is then repositioned to place the prosthesis in the desired deployment location. Proper placement may be facilitated with the use of radiopaque markers as

described above. Balloon catheter **104** is then extended such that balloon **107** is above renal arteries **180**. Balloon **107** is then inflated to occlude the aorta as shown in FIG. **12**.

While maintaining proximal portion pusher **102** in a fixed position, outer sheath **101** is withdrawn until the proximal end of the prosthesis emerges from outer sheath **101** as shown in FIG. **13**. Using a radiopaque marker **120** disposed on proximal end of the prosthesis, the introducer is rotated until proper alignment of the prosthesis is obtained. In the illustrated embodiment, radiopaque marker **120** is a platinum wire twisted around an apex of the prosthesis in a "V" shape. To ensure proper alignment, the stent should be rotated until only the profile of the V is seen and shows up as a straight line rather than a "V".

Outer sheath **101** is further withdrawn while maintaining proximal portion pusher **102** fixed until proximal portion **12** is fully deployed from the end of outer sheath **101**, and the frustoconical portion **18** of the prosthesis just clears end **117**, as shown in FIG. **14**.

Balloon **107** is then deflated to allow blood to flow through proximal portion **12** and out frustoconical portion **18** of the prosthesis. Balloon **107** is withdrawn into the prosthesis until the distal end **118** of nose cone **106** is just above the proximal end of the prosthesis. Balloon **107** is then inflated to seat the prosthesis, which may be provided with barbs (not shown) at its proximal end, against the wall of the aorta, as shown in FIG. **15**.

Distal portion pusher **103** is then maintained in a fixed position while outer sheath **101** is withdrawn. Once outer sheath **101** has been withdrawn to the point at which proximal end **117** of outer sheath **101** is flush with proximal end **115** of proximal portion pusher **102**, both outer sheath **101** and proximal portion pusher **102** are withdrawn, still maintaining distal portion pusher **103** in a fixed position. Outer sheath **101** and proximal portion pusher **102** are withdrawn until distal portion **16** of the prosthesis is deployed clear of proximal end **116** of distal portion pusher **103** as shown in FIG. **16**. Balloon **107** is slowly deflated to allow blood flow to be established through the proximal portion **12** of the prosthesis and out through frustoconical portion **18**. Balloon **107** may be used to model distal portion **16** of the prosthesis as necessary by inflating balloon **107** where needed to expand distal portion **16**. Balloon **107** is then deflated, and introducer **100** is withdrawn from the vasculature, leaving the guide wire **170** in place, as shown in FIG. **17**.

FIG. **21**(*a*) illustrates an exemplary second introducer **300** used for deploying second distal part **44**. Second introducer **300** of the illustrated embodiment comprises cylindrical outer sheath **301** and female Luer lock assembly **310**. Second introducer **300** also has hemostasis valve **361** contained within a hub **362** thereof. Cartridge **311** shown in FIG. **21**(*b*) is adapted to be attached to second introducer **300**. Cartridge **311** has threaded male Luer lock assembly **312** provided on its proximal end. Cartridge **311** has outer tube **313** which houses inner tube **314**.

In use, a thin-walled tube (not shown) is first threaded through distal portion **44**. This tube serves as a guide wire guide, allowing a guide wire to be threaded straight through distal portion **44** as discussed below. Distal portion **44** containing the thin-walled tube is then cooled, radially compressed, and inserted into inner tube **314** of cartridge **311** in a manner similar to that described for inserting the bifurcated prosthesis into proximal portion pusher **102** and outer sheath **101**. When distal portion **44** has been loaded into inner tube **314** of cartridge **311**, the thin-walled tube serving as a guide wire guide extends out both ends of cartridge **311**.

A guide wire **171** is then inserted into the vasculature to the bifurcation site and through distal stent portion **12** as shown in FIG. **18**. A dialator **359** (FIG. **21**(*c*)) having an outer diameter slightly less than the inner diameter of second introducer **300** is then inserted into second introducer **300** such that tapered end **360** extends out end **320** of second introducer **300**. End **360** of dialator **359** has a hole therein that is just slightly larger than guide wire **171** and tapers gradually outward from the hole to the outer diameter of dialator **359**.

Second introducer **300** is then inserted into the vasculature over guide wire **171** by passing guide wire **171** into and through dialator **359**. Dialator **359** with tapered end **360** provides a smooth transition within the blood vessel from the diameter of guide wire **171** to the diameter of second introducer **300**. Second introducer **300** is maneuvered such that outer sheath **301** is inside frustoconical portion **18** of proximal portion **12** by at least 20 mm in this embodiment, as shown in FIG. **19**. Dialator **359** is then removed from second introducer **300** and from the vasculature and is discarded.

Cartridge **311** is then passed over guide wire **171** by passing guide wire **171** through the thin-walled guide wire guide within distal portion **44** contained in cartridge **311**. The guide wire guide is then removed and discarded.

Cartridge **311** is then lockingly engaged with introducer **300** by mating male Luer lock assembly **310** with female luer lock assembly **312**. Such locking engagement prevents relative movement of cartridge **311** and introducer **300**. Preventing relative movement lends stability and reliability to the insertion process that has not heretofore been achieved.

A pusher **315** is then inserted into inner tube **314** of cartridge **311** such that proximal end **317** of pusher **315** longitudinally contacts a distal end of distal portion **44** within inner tube **314**. Pusher **315** pushes distal portion **44** through cartridge **311** and into outer sheath **301** of introducer **300**. Distal portion **44** is pushed through outer sheath **301**, which remains in a fixed position, until distal portion **44** is at proximal end **320** of outer sheath **301** (see FIG. **19**). Again, radiopaque markers **120** may be used to align distal portion **44** properly with proximal portion **12**.

Pusher **302** is held firmly in place, and outer sheath **301** is withdrawn approximately 2 cm. This deploys frustoconical part **42** of distal part **44** inside the frustoconical part **18** as shown in FIG. **19**. The outer surface of frustoconical part **42** engages the inner surface of frustoconical part **18** such that distal portion **44** is connected to proximal portion **12** to resist longitudinal separation.

Outer sheath **301** may then be withdrawn while maintaining pusher **302** in a fixed position to fully deploy distal portion **44**, as shown in FIG. **20**. If necessary, balloon catheter **104** may be inserted through sheath **301** in order to model distal portion **44**. Introducer **301** and guide wires **170**, **171** are then removed from the vasculature and the entry points are closed.

The delivery apparatus and method described above are particularly useful in treating an abdominal aortic aneurysm with a bifurcated prosthesis according to the present invention. Other diseases and alternative embodiments of the prosthesis and delivery method will now be described.

In the case of an abdominal aortic aneurysm confined to the aorta and not extending far enough to affect the iliac arteries, a straight (i.e. non-bifurcated) stent may be used.

Preferably, for such applications, the straight stent comprises a composite of at least two axially aligned stent segments. Two embodiments of such straight stents are described herein, each comprising axially aligned stent requests, each of the requests comprising one or more adjacent hoops, perpendicular to a common axis, and each hoop being formed of wire in a sinuous or zigzag configuration with some or all of the juxtaposed apices in adjacent hoops secured to one another.

First, referring to FIG. **22**, straight stent **400** comprises proximal stent portion (or segment) **401**, distal stent portion **402**, and an intermediate portion **403**.

Proximal portion **401** is a ring formed of a number of longitudinally spaced hoops **20** as described in connection with the formation of stent **10** above. In the illustrated embodiment, two hoops **20** are used, each hoop **20** having a unit width.

Distal portion **402** is also a ring formed of longitudinally displaced hoops **20** in the manner described above. Distal ring **402** has two hoops **20** of unit width in the illustrated embodiment.

Intermediate portion **403** of straight stent **400** is formed of biocompatible woven fabric such as, for example, a plain woven fabric made from 30 or 40 denier polyester. In this embodiment, intermediate fabric section **403** does not cover a stent. Fabric portion **403** is attached at its proximal and distal ends to the proximal and distal stent portions, respectively, by stitching, for example, with 0.003 inch polypropylene filaments around apices **22** of the stent portions. Other than such connections at its longitudinal ends, intermediate fabric section **403** is unsupported by any stent.

The second embodiment of a straight stent that may be used according to this invention is illustrated in FIG. **23**. Straight stent **450** includes stent portion **451**, constructed of wire loops as described above with reference to stent portions **401** and **402**. Stent portion **451** is partially covered by fabric **452**. In this embodiment, fabric portion **451** covers and is supported by stent **451**, whereas with stent **400**, the fabric portion **403** is not supported by a stent.

To treat an abdominal aortic aneurysm that does not extend down over the walls of the iliac arteries, as shown in FIG. **24**(*a*), straight stent **400** (or **450**) is disposed as illustrated in FIG. **26**. Proximal stent portion **401** engages the inner walls of the aorta above the aneurysm. Distal stent portion **402** engages the inner wall of the aorta below the aneurysm. Intermediate fabric portion **403** extends across the aneurysm, providing a strong, stable lumen for blood flow through the aorta.

FIG. **28** illustrates the delivery apparatus used to implant straight stent **400** in the vasculature. This apparatus is very similar to that described above for the delivery system to be used with the bifurcated stent or prosthesis. Accordingly, like reference numerals refer to the same components.

In the introducer **410** shown in FIG. **28**, proximal portion pusher **102** engages proximal stent portion **401**. Distal portion pusher **103** engages distal stent portion **402**.

In use, straight stent **400** is first charged into the introducer by cooling it to temperatures below 10° C., radially compressing it, and inserting it within outer sheath **101**, as described above in connection with the bifurcated stent or prosthesis. The remainder of introducer **410** is also assembled as described in connection with introducer **100**.

Introducer **410** is passed through an entry point (not shown) over guide wire **411** as shown in FIG. **24**(*a*). This insertion may be accomplished using percutaneous or cut-down techniques. Introducer **410** is then inserted to the desired delivery location.

In the aorta, introducer **410** is positioned and balloon **107** is inflated above the renal arteries in the same manner as described above in connection with the bifurcated stent and as illustrated in FIG. **24**(*a*).

While maintaining proximal portion pusher **102** in a fixed position, outer sheath **101** is withdrawn until proximal portion **401** of stent **400** emerges from outer sheath **101** as shown in FIG. **24**(*b*). Using a radiopaque marker **420** disposed on the proximal end of the proximal portion **401**, stent **400** is optimally aligned within the aorta. Outer sheath **101** is further withdrawn until proximal portion **401** emerges therefrom, as shown in FIG. **25**. Outer sheath **101** is then further withdrawn until it is flush with proximal portion pusher **102**. Then both outer sheath **101** and proximal portion pusher **102** are withdrawn while maintaining distal portion pusher **103** in a fixed position. Distal portion **402** is thus deployed from the end of outer sheath **101**, as shown in FIG. **26**.

Balloon **107** is then deflated and withdrawn inside proximal portion **401** where balloon **107** is reinflated to seat the stent **400**, as shown in FIG. **27**. Balloon **107** is then withdrawn, along with the introducer **410** as described above, and the entry point is closed.

FIG. **29** illustrates the apparatus used to deploy straight stent **450**, shown in FIG. **23**, of the present invention. This apparatus is very similar to that described above for the delivery system to be used with the bifurcated stent or prosthesis. Accordingly, like reference numerals refer to the same components.

Proximal portion pusher **102** in this embodiment is glued to distal portion pusher **103** such that ends **115** and **116** are flush. These flush ends are adapted to engage stent **450** within outer sheath **101**.

In use, straight stent **450** is first charged into introducer **490** by cooling it to temperatures below 10° C., radially compressing it, and inserting it within outer sheath **101**, as described above in connection with the bifurcated stent or prosthesis. The remainder of introducer **490** is also assembled as described in connection with introducer **100**.

Introducer **490** is passed through an entry point (not shown) over a guide wire **411** as shown in FIG. **30**. This insertion may be accomplished using percutaneous or cut-down techniques. Introducer **490** is then inserted to the desired delivery location.

In the aorta, introducer **490** is positioned and balloon **107** is inflated above the renal arteries in the same manner as described above in connection with the bifurcated stent and as illustrated in FIG. **31**.

While maintaining attached proximal portion pusher **102** and distal portion pusher **103** in a fixed position, outer sheath **101** is withdrawn until proximal portion **451** of stent **450** emerges from outer sheath **101** as shown in FIG. **32**. Using a radiopaque marker **420** disposed on the proximal end of the proximal portion **451**, stent **450** is optimally aligned within the aorta. Outer sheath **101** is then completely withdrawn until stent **450** is deployed into the aorta as shown in FIG. **33**.

Balloon **107** is then deflated and withdrawn inside proximal portion **451** where balloon **107** is re-inflated to seat the stent **450**, as shown in FIG. **34**. Balloon **107** is then withdrawn, along with the introducer **490** as described above, and the entry point is closed.

The angeological disease of occlusion is the blockage of an artery resulting from a buildup or clot of soft thrombus.

There are two types of occlusions that can occur at the aorta-iliac bifurcation. The first is infrarenal occlusion. In this case, the blockage extends in the aorta from just below the renal arteries into the iliac arteries. The second type is an occlusion that is limited to the immediate area of the bifurcation.

To treat an infrarenal occlusion, a canalization is first made through the thrombus by methods known in the art. A bifurcated endoluminal prosthesis according to the present invention is then implanted at the bifurcation site to provide an unobstructed lumen extending from the aorta into each of the iliac arteries. Blood can thus flow freely from the aorta to the iliac arteries.

The bifurcated endoluminal prosthesis according to the present invention that is used to treat an occlusion must be fabric covered. This is necessary to prevent embolization from the thrombus remaining on the wall of the recanalized artery.

An occlusion at the bifurcation is treated by recanalizing the artery as above. A bifurcated endoluminal prosthesis according to the present invention may be implanted at the bifurcation. Because the occlusion is limited to the immediate bifurcation site, however, the proximal portion of the prosthesis may be shorter than that discussed above.

To implant the bifurcated endoluminal prosthesis to treat both types of occlusion, the delivery system comprising introducer **100** discussed above for delivering the bifurcated endoluminal prosthesis to treat an abdominal aortic aneurysm is used. The same delivery method discussed above for implanting the bifurcated endoluminal prosthesis to treat abdominal aortic aneurysms is used to implant the device to treat the occlusion.

Using the method and apparatus of this invention to treat occlusion provides an unobstructed lumen through which blood can flow from the aorta to the iliac arteries.

The angeological disease of stenosis is a narrowing of an artery caused by a buildup of hard calcified plaque. This is usually caused by a buildup of cholesterol. To treat such an angeological disease, angioplasty is performed on the plaque according to methods well known in the art. The bifurcated endoluminal stent according to the present invention is then implanted at the bifurcation site. This stent is the same as that described above for treatment of an abdominal aortic aneurysm. To treat the stenosis, however, it is not necessary to cover the stent with a fabric, thus creating a prosthesis. Because restenosis is rare at the bifurcation site, there is no need to isolate the blood flowing in the lumen from the walls of the arteries.

The delivery system used to implant the bifurcated endoluminal stent used to treat stenosis is the same as that illustrated in FIG. **8** except that balloon **107** is not required. Because there is no fabric around the stent to be affected by blood flow in the arteries and cause migration of the bifurcated stent, it is not necessary to block the blood flow with the balloon. Otherwise, the delivery system for implanting the bifurcated stent to treat stenosis is the same as that for implanting the bifurcated prosthesis to treat abdominal aortic aneurysm.

Similarly, with the exception of the steps involving inflation of balloon **107** to block blood flow, the method of delivering the bifurcated endoluminal stent to treat stenosis is the same as that described above for delivering the bifurcated endoluminal prosthesis to treat abdominal aortic aneurysm.

What is claimed:

**1**. A method for delivering a bifurcated endoluminal stent or prosthesis to a bifurcation site where a blood vessel branches into a first branched vessel and a second branched vessel, said method comprising the steps of:

(a) providing a first section of said bifurcated endoluminal stent or prosthesis including a proximal portion and a first distal portion;

(b) providing a first introducer having an outer sheath, a proximal portion pusher disposed at least partially within said outer sheath, and a distal portion pusher disposed at least partially within said proximal portion pusher;

(c) placing said first section of said bifurcated endoluminal stent or prosthesis within said first introducer such that said proximal portion of said first section of said bifurcated endoluminal stent or prosthesis is disposed within said outer sheath, and such that said distal portion of said bifurcated endoluminal stent or prosthesis is disposed within said proximal portion pusher;

(d) inserting said first introducer containing said first section of said bifurcated endoluminal stent or prosthesis into a body to a predetermined delivery location at said bifurcation site;

(e) partially withdrawing said outer sheath of said first introducer while maintaining said proximal portion pusher in a fixed position until said proximal portion of said first section of said bifurcated endoluminal stent or prosthesis is deployed from said first introducer into said blood vessel at said bifurcation site;

(f) further withdrawing said outer sheath and partially withdrawing said proximal portion pusher while maintaining said distal portion pusher in a fixed position until said first distal portion of said first section of said bifurcated endoluminal stent or prosthesis is deployed from said first introducer at least partially into said first branched vessel;

(g) fully withdrawing said first introducer from the body;

(h) providing a second section of said bifurcated endoluminal stent or prosthesis including a second distal portion;

(i) providing a second introducer having an outer sheath and a pusher disposed at least partially within said outer sheath;

(j) placing said second section of said bifurcated endoluminal stent or prosthesis within the outer sheath of said second introducer;

(k) inserting said second introducer containing said second section of said bifurcated endoluminal stent or prosthesis into the body to said bifurcation site;

(l) partially withdrawing said outer sheath of said second introducer while maintaining said pusher of said second introducer in a fixed position until said second distal portion of said second section of said bifurcated endoluminal stent or prosthesis is deployed from said second introducer such that a proximal end of said second distal portion securely connects to said proximal portion of said first section of said bifurcated endoluminal stent or prosthesis, and such that a distal end of said second distal portion extends at least partially into said second branched vessel; and

(m) fully withdrawing said second introducer from the body.

**2**. A method for delivering a bifurcated endoluminal stent or prosthesis as claimed in claim **1** wherein said first introducer further comprises a balloon catheter having a balloon attached thereto and said method further comprises the step of inflating said balloon inside said bifurcated endoluminal stent or prosthesis after said bifurcated endoluminal stent or prosthesis is deployed at said bifurcation site in order to model said bifurcated endoluminal stent or prosthesis.

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UNITED STATES PATENT AND TRADEMARK OFFICE

# CERTIFICATE OF CORRECTION

PATENT NO. : 5,609,627
DATED : March 11, 1997
INVENTOR(S) : Goicoechea, et. al.

It is certified that error appears in the above-indentified patent and that said Letters Patent is hereby corrected as shown below:

Title page, item [30] Foreign Application Priority Data should read --94400284.9 and 94401306.9--.

Title page, under "Other Publications", at "Cragg et al.," delete "International" and insert therefor --Interventional--.

Signed and Sealed this

Twenty-eighth Day of July, 1998

*Attest:*

BRUCE LEHMAN

*Attesting Officer*

*Commissioner of Patents and Trademarks*